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No. 08-

IN THE

Supreme Court of the United States

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L., *et al.*,

Petitioners,

v.

BAYER AG AND BAYER CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Are pharmaceutical "reverse payment" agreements — whereby the manufacturer of a brand-name drug (and patent holder) pays a generic manufacturer (and alleged patent infringer) to not launch a generic version of the brand-name drug — *per se* lawful without regard to the amount of cash paid or the strength of the underlying patent challenge?

PARTIES TO THE PROCEEDING

Petitioners, plaintiffs below, are consumers of Cipro® (ciprofloxacin hydrochloride) and third-party payor entities that purchased, paid for, and/or reimbursed for Cipro®.[1] Respondents, defendants below, are a brand-name pharmaceutical manufacturer, Bayer AG, and its United States subsidiary Bayer Corporation ("Bayer US" and, together with Bayer AG, "Bayer"); a generic pharmaceutical manufacturer, Barr Laboratories, Inc. ("Barr"); and Barr's partners relative to its efforts to market generic ciprofloxacin hydrochloride, *i.e.*, The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR" but now known as Aventis Pharmaceuticals Inc.); and, Watson Pharmaceuticals Inc. ("Watson"). Collectively, all respondents are referred to herein as "Defendants."

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1. The Petitioners are: (1) Arkansas Carpenters Health and Welfare Fund; (2) A.F. of L. - A.G.C. Building Trades Welfare Plan; (3) Mark Aston; (4) Board of Trustees of the United Food & Commercial Workers of Arizona Health and Welfare Fund; (5) Adele Brody; (6) Michelle Cross; (7) Donna Franck; (8) Kristine Gaddis; (9) David Green; (10) IBEW-NECA Local 505 Health & Welfare Plan; (11) John H. Irons; (12) Local 1199 National Benefit Fund for Health and Human Services Employees; (13) Maria LoCurto; (14) Caroline M. Loesch; (15) Kimberly McCullar; (16) Linda K. McIntyre; (17) Mechanical Contractors - UA Local 119 Welfare Plan; (18) Theresa Meyers; (19) Patricia Nelson; (20) Frances Norris; (21) Paper, Allied-Industrial, Chemical and Energy Workers International Union, AFL-CIO, CLC; (22) Mary Ann Scott; (23) Sheet Metal Workers Local 441 Health & Welfare Plan; (24) Maurice Stewart; (25) Ann Stuart; (26) United Food & Commercial Workers and Participating Food Industry Employers Tri-State Health & Welfare Fund; and (27) Vista Healthplan, Inc.

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PETITION FOR WRIT OF CERTIORARI

Petitoners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Court of Appeals' October 15, 2008 opinion (Pet. App. 1a- 35a) is reported at 544 F.3d 1328. On December 23, 2008, the Court of Appeals denied rehearing and *en banc* rehearing in an unreported order (Pet. App. 116a). The opinion of the district court granting the Defendants' motions for summary judgment (Pet. App. 39a-115a) is reported at 360 F. Supp. 2d 514.

JURISDICTION

The judgment of the Court of Appeals was entered on October 15, 2008. A petition for rehearing was denied December 23, 2008. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. §§ 1, 2; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. N. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet App. 119a-141a.

STATEMENT OF THE CASE

The Court should review this case and determine the antitrust standard applicable to pharmaceutical "reverse payment" agreements that are commonly used to delay the launch of generic versions of brand-name drugs. Under such agreements, the manufacturers of branded drugs (who are patent holders) pay millions — or, as in this case, *hundreds* of millions — of dollars to generic pharmaceutical manufacturers (who are alleged patent infringers) to delay the launch of generic versions of the branded drugs. The fact that the *plaintiffs* in patent infringement litigation are paying cash to the *defendants, i.e.*, the payments are "reversed" from the usual, suggests that the parties are engaged in market allocation rather than a bona fide settlement of litigation. The Courts of Appeals that have addressed these agreements have rendered inconsistent and irreconcilable decisions on a matter of fundamental importance to public health and welfare.

In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, __ U.S. __, 127 S. Ct. 3001 (2007), the Second Circuit held that reverse payment agreements are beyond the reach of antitrust scrutiny and, for all practical purposes, *per se* legal. In reaching this conclusion, the Second Circuit relied heavily on the district court decision that has now been affirmed the Federal Circuit in this case, *see* 466 F.3d at 204-213 (citing Pet. App. 67a-91a). In contrast, the Sixth Circuit considers such agreements *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The Eleventh Circuit applies its own test that inquires into

the validity of the underlying patent at the time of the exclusion payment before evaluating the antitrust implications of a reverse payment agreement. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

In the petition for certiorari that followed the *Tamoxifen* decision (No. 06-830), the United States (by the Solicitor General) agreed that "[t]he petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market by the alleged infringer in exchange for a 'reverse payment' from the patent holder." Brief for the United States as Amicus Curiae in *Joblove v. Barr Labs.*, No. 06-830, 2007 WL 1511527 (dated May 2007) ("US Brief in *Tamoxifen*") at 8. According to the United States, the Second Circuit "applied an insufficiently stringent standard in scrutinizing the settlement at issue here." *Id.*[2]

That same "insufficiently stringent standard" was followed by the Federal Circuit below. Pet. App. 23a-24a.[3]

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2. The United States nonetheless recommended against certiorari in *Tamoxifen* on grounds that are inapplicable to the instant petition. See pp. 15-19, *infra*.

3. The Federal Circuit applies the law of the regional circuit, in this case, the Second Circuit, to the elements of antitrust claims that are not unique to patent law. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067-68 (Fed. Cir. 1998) (en banc in relevant part). The appeal in this case was transferred from the Second Circuit to the Federal Circuit as a

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The inconsistency in the approaches taken by the Courts of Appeals, as well as by antitrust enforcement authorities, continues to create enormous uncertainty, preventing clarity both in antitrust counseling and in the litigation of frequently recurring antitrust issues in the pharmaceutical field.

A. Petitioners Have Demonstrated a Horizontal Market-Allocation Agreement That Violates Federal and State Antitrust Law.

The core antitrust allegations in this litigation spring from agreements reached among several of the Defendants in a *prior* litigation. Bayer owns U.S. Patent No. 4,670,444 (the "'444 Patent"), the compound patent that claims ciprofloxacin. Barr is a competitor of Bayer's that manufactures and markets generic versions of brand-name drugs.

In 1991, Barr filed an application with the United States Food and Drug Administration ("FDA") seeking regulatory approval to sell a generic version of Cipro. In its application, Barr challenged the validity and enforceability of the '444 Patent, which prompted Bayer to sue Barr for infringement (the "*Bayer v. Barr* Patent

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result of *Walker Process*-like claims unrelated to the challenged reverse payment agreements. *See* Pet. App. 36a-38a. In fact, the Second Circuit denied transfer of appeals by drug wholesalers and retailers from the same summary judgment decision at issue here, but who did not bring *Walker Process* monopolization claims. *Id.* at 37a. As of the date of this petition, those appeals remain pending in the Second Circuit [2d Cir. Nos. 05-2851 & 05-2852].

Litigation"). Were Barr to succeed in invalidating the '444 Patent, it would have made millions of dollars upon entering the ciprofloxacin market and sharply undercutting Bayer's price for Cipro. And Cipro consumers and third-party payors would benefit from the lower prices offered by Barr and other generic competitors entering the market with ciprofloxacin products. For its part, Bayer would see its lucrative Cipro monopoly, which was then yielding nearly $1 billion per year, virtually vanish.

To avoid the risk of that result, Bayer instead bought the result it wanted. On the eve of trial the parties settled the *Bayer v. Barr* Patent Litigation by entering into a series of agreements (the "Cipro Agreements"), pursuant to which Bayer, the patent holder, paid out $398 million to Barr, the alleged infringer and, directly or indirectly, to the other defendants. In exchange for these payments (referred to by the district court as "reverse payments" or "exclusion payments" (*see* Pet. App. 47a)), Barr and the other Defendants agreed not to manufacture or market any generic versions of Cipro during the life of the '444 Patent. *Id.* at 45a. Thus, Bayer was able to exclude competitors not by *enforcing* its patent, but by *ceasing* to enforce its patent and instead paying its competitors to abandon the market.

B. Defendants Co-Opted the Hatch-Waxman Act For Their Anticompetitive Purposes.

Defendants' unlawful conduct in entering into the Cipro Agreements should be considered in context. The only reason the litigation between Bayer and Barr could proceed in the first place was because specific federal legislation – the Hatch-Waxman Act – permitted, and indeed encouraged it. A company seeking to market a new prescription drug in the United States must secure approval from the FDA. 21 U.S.C. § 355(a). In 1984, Congress passed the Hatch-Waxman Act, 21 U.S.C. § 355(j), which amended the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, to establish an abbreviated process to expedite the development, approval and marketing of generic drugs. *See Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.") (citation omitted). Hatch-Waxman permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") that incorporates by reference safety and efficacy data developed and previously submitted by the "pioneer" or brand-name drug manufacturer. An ANDA filer must demonstrate that its product is "bioequivalent" to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv).

An ANDA filer must make one of four certifications in its ANDA, two of which matter here, *i.e.*, the "Paragraph III Certification," which states that the patent for the pioneer drug listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") will

expire on a particular date and the ANDA filer does not seek FDA approval of its ANDA before that date, and the "Paragraph IV Certification," which states that the patent listed in the Orange Book is invalid or will not be infringed by the sale of the generic company's product. 21 U.S.C. § 355(j)(2)(A)(vii).

An ANDA applicant making a Paragraph IV Certification (an "ANDA(IV) filer") must notify the patent owner (the "ANDA Notification"). 21 U.S.C. § 355(j)(2)(B). Thereafter, the patent holder may initiate a patent infringement suit against the ANDA(IV) filer; if an infringement action is initiated within 45 days, the FDA is forbidden from granting final approval to the ANDA until: (1) the patent expires; (2) the expiration of 30 months from the ANDA Notification (the "30-Month Stay"); or (3) a final judicial determination of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iii).

To encourage patent challenges, the first ANDA(IV) filer is eligible for a 180-day period as the exclusive producer of the generic formulation of the pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period will not begin to run until triggered by either: the commercial marketing of the generic drug by the first ANDA(IV) filer; or a decision of a court finding the pioneer drug's patent to be invalid, unenforceable or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107. Until the 180-day exclusivity period has been triggered and run its course, the FDA is prevented from approving any other ANDA. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

As Barr was the first ANDA(IV) filer, Bayer also bought Barr's cooperation in manipulating the exclusivity period for their joint benefit and to the detriment of other generic competitors. The Cipro Agreements required Barr to withdraw its Paragraph IV Certification and replace it with a Paragraph III Certification. However, Barr retained the option to refile a Paragraph IV Certification in the event a competitor successfully challenged the '444 Patent. This worked as a disincentive for other competitors because it removed the financial incentive of the exclusivity period and introduced the prospect of additional delay before market entry. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553, 1586 (Nov. 2006) ("Generic firms other than the first filer will be behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue the challenge.").

In entering the Cipro Agreements, Defendants turned Hatch-Waxman – the "Drug Price Competition" statute – on its head, delaying generic entry into the ciprofloxacin market and ensuring that consumers and their prescription drug benefit providers would pay *more than ever* for Cipro. With its monopoly intact, Bayer raised the price of Cipro to fund its exorbitant exit payments to Barr and the other defendants. Indeed, to call the Cipro Agreements a "settlement" ignores economic reality; Barr and its litigation partners made more from the exit payments than they would have made

had they invalidated the '444 Patent and entered the market with a competing generic product.[4]

C. The Course of the Proceedings and the Disposition in The District Court.

In 2000 and 2001, antitrust actions challenging the Cipro Agreements were filed in state and federal courts. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation centralized all cases in the United States District Court for the Eastern District of New York, before the Hon. David G. Trager. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, MDL No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001).

On October 1, 2001, the district court remanded nine cases to various state courts, and retained jurisdiction over two cases that satisfied the requirements for diversity jurisdiction. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001). On December 18, 2001, Petitioners filed an amended consolidated class action complaint that asserted claims for injunctive and declaratory relief for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and for damages under state law.[5]

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4. For example, Petitioners' economic expert opined that $398 million was more than twice the but-for profits that Barr could have reasonably expected to earn. *See* Fed. Cir. Appendix A-3426-28.

5. It is well recognized that conduct that violates Sections 1 and 2 of the Sherman Act also will violate most corresponding state antitrust statutes. *United States v. Microsoft Corp.*, (Cont'd)

On May 20, 2003, the district court, *inter alia*, granted Watson's motion to dismiss all claims against it for failure to state a claim. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

On March 31, 2005, the district court granted Bayer's partial summary judgment motion and Barr's, Rugby's and HMR's joint summary judgment motion, dismissing Counts I through IV of the Complaint, and granted Bayer's motion to dismiss Count V of the Complaint. Pet. App. 39a-115a.

Final judgment was entered on April 8, 2005, and after being granted an extension of time within which to file an appeal, Petitioners timely filed a Notice of Appeal to the Second Circuit on June 6, 2005.

On November 11, 2007, the Second Circuit granted Defendants' motion to transfer Petitioners' appeal (2d Cir. No. 05-2863) to the Federal Circuit. Pet. App. 36a-38a. In that same order, the Second Circuit denied

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87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000) ("The facts proving that Microsoft unlawfully maintained its monopoly power in violation of § 2 of the Sherman Act are sufficient to meet analogous elements of causes of action arising under the laws of each plaintiff state.") (footnote citing eighteen state statutes omitted), *affirmed in part rev'd in part on other grounds by*, 253 F.2d 34 (D.C. Cir. 2001). In fact, many state antitrust statutes expressly adopt federal antitrust precedents as controlling guidance. *E.g.*, Ariz. Rev. Stat. § 44-1412; D.C. Code Ann. § 28-4515; Iowa Code § 553.2; N.M. Stat. Ann. § 57-1-15; S.D. Codified Laws § 37-1-22; W. Va. Code Ann. § 47-18-16.

Defendants' motion to transfer related appeals filed by drug wholesalers and retailers (2d Cir. Nos. 05-2851 & 05-2852). Those appeals remain pending in the Second Circuit, resulting in the extraordinary circumstance of two distinct appeals, to different Circuits, from the same summary judgment order.

D. The Disposition by the Federal Circuit.

On October 15, 2008, a panel of the Federal Circuit affirmed judgment in favor of Defendants. Pet. App. 1a-35a. Following the Second Circuit decision in *Tamoxifen* (which followed the district court opinion that was affirmed by the Federal Circuit below), the panel agreed that "any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law." Pet. App. 3a.

> We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.

Pet. App. 23a-24a (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965)).

REASONS FOR GRANTING THE PETITION

Review by this Court is necessary to reconcile conflicting standards adopted by the Courts of Appeals relative to a matter of vital importance to all Americans, *i.e.*, the escalating cost of prescription drugs. The disagreements among the circuits, on an issue of such basic importance, will continue to cause uncertainty, litigation and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to purchase needed medications.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs — chemically and pharmacologically identical but lacking a brand-name — are much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration; An FTC Study* 9 (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. When generic versions of popular brand-name drugs are launched, the generics quickly capture the bulk of the market, saving consumers billions of dollars. *See* Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, July 20, 2006 ("FTC July 2006

Statement")[6], p. 6 ("As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of the lower-priced generic product.") (footnote omitted); *Sanofi-Syntholabo v. Apotex Inc.*, No. 02-2255, 2006 WL 2516486, at *25 (S.D.N.Y. Aug. 31, 2006) (generic version of popular brand-name drug Plavix captured 78.4% of sales within three weeks).

A delay in the launch of a generic version of a widely prescribed drug forces consumers to pay millions of dollars *a day* in monopoly rents. Thus, brand-name manufacturers have become adept at abusing the Hatch-Waxman regime to block, frustrate and delay generic entry. When all else fails, brand companies often pay cash to forestall competition. *See* pp. 25-26, *infra*. In the end, consumers must pay higher prices for branded drugs for longer periods as a result of a patent challenge originally launched under the provisions of the Hatch-Waxman Act.

> These settlements, which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market is product. Although both the brand company and the generic company are better off financially, these settlements

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6. *Available at:* http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf.

> restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

FTC July 2006 Statement, p. 5-6.

Under the standard set forth in the decision below and *Tamoxifen*, antitrust scrutiny of pharmaceutical reverse payment agreements will be limited to: (1) whether infringement claims based on the patent at issue constitute a "sham" or fraud; and (2) whether the agreement is limited to the facial scope of the patent. *See* Pet. App. 23a-24a; *Tamoxifen*, 466 F.3d at 208-09. Review under the Sixth and Eleventh Circuit standards require markedly different approaches. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (reverse payment agreements *per se* illegal); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (rule of reason inquiry into the strength of the patent at the time of the reverse payment); pp. 20-22, *infra*.

In addition to the inconsistent positions of the Courts of Appeals, the FTC has advanced a "rule of reason" inquiry that does not require direct analysis of the patent merits at all, at least in government enforcement proceedings, but instead focuses on the existence and amount of the reverse payment and other circumstantial factors. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (rejecting the FTC's approach), *cert. denied*, 548 U.S. 919 (2006). The United States (through the Solicitor General), has stated that

"[i]n determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims viewed ex ante." US Brief in *Tamoxifen* at 12; *accord* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 11.

The Court should accept review of this case to resolve the stark inconsistency in circuit and other authority.[7]

This case also provides an appropriate context in which to consider the question presented. In *Tamoxifen*, the Solicitor General opined that "[a]lthough the court of appeals applied an erroneous standard for scrutinizing patent infringement settlements that include reverse payments, this case is not an attractive vehicle for the Court's consideration of the difficult and context-sensitive questions involved in assessing the legality of such settlements." US Brief in *Tamoxifen* at 16-17. For at least four reasons, a different conclusion is appropriate in this case.

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7. The Court could adopt the standard articulated by one of the Courts of Appeals or government agencies, or possibly establish another, such as those suggested by antitrust scholars. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006). There, Professor Hemphill maintains that the FTC, the Eleventh Circuit and the Second Circuit incorrectly analyze these cases in terms of whether the patent or antitrust laws should be accorded primacy, because: (1) the Hatch-Waxman Act established a regulatory regime that trumps the patent law in that particular context; and (2) the issue is how the antitrust laws should be applied under that regulatory regime (not under the patent laws).

First, the Solicitor General rested his conclusion largely on an assertion that the factual setting in *Tamoxifen* was "atypical and unlikely to recur" because "[t]he fact that the settlement at issue in this case occurred after a judgment of invalidity highlights the court of appeals' error in refusing to assess the validity of the patent, and might play a substantial role in the Court's analysis of the merits." *Id.* at 19. By contrast, in this case there was no such finding of patent invalidity prior to the settlement, and no such finding was vacated in connection with the settlement. Thus, this central aspect of the Solicitor General's arguments against a grant of certiorari in *Tamoxifen* is completely inapplicable in this case.

Second, the Solicitor General opined in *Tamoxifen* that the federal injunctive claims appeared to be moot – despite the established rule that an injunction can properly enjoin a repeated antitrust offender from engaging in similar unlawful practices even after the challenged conduct has ceased as to the specific matters at issue in a case[8] — based on the hypothesis that the

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8. *See, Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 133 (1969)("[W]hen one has been found to have committed acts in violation of the law he may be restrained from committing other related unlawful acts."); *United States v. W.T. Grant Co.*, 345 U.S. 629, 632-33 (1953)("The defendant is free to return to his old ways. This, together with a public interest in having the legality of the practices settled, militates against a mootness conclusion."); *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000)("It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power

(Cont'd)

issue might be considered in a later case, in the event of further unlawful behavior by the repeatedly wrongdoing defendant, because *other* patents held by that defendant might not expire before the plaintiffs "could obtain relief." US Brief in *Tamoxifen* at 17. However, respondent Barr Laboratories, Inc. was a defendants both in this case and in *Tamoxifen*. That the patent in this case expired prior to the petition for certiorari here, just as occurred in *Tamoxifen*, tends to confirm that patents at issue in these cases will often expire prior to an opportunity for review by this Court, thereby causing the issue of unlawfulness of the conduct to "evade review" if the injunctive claims are regarded as moot merely because the particular patent in question expires before a petition for certiorari is considered.

Third, an examination of the Federal Circuit's decision gives no indication whatsoever that it believed

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(Cont'd)

to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur."). Respondent Barr Labs., Inc. is the foremost example of a reverse payment recidivist, having been party to a large number of reverse payment agreements. *See* C. Scott Hemphill, *Drug Patent Settlements Between Rivals, A Survey*, at 3 (Mar. 12, 2007) attached to Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Hearing on H.R. 1902, May 2, 2007, available at: *http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf*. ("Of the seventeen innovators and eighteen generic firms that are party to the settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlement with respect to eight different drugs.").

its decision stemmed from anything specific in the state laws under which the damage claims are asserted. Indeed, the Federal Circuit's decision, just like that of the District Court, analyzes the reverse payment claims in this case entirely as though they were asserted *under federal law* rather than state law. *See* Pet. App. 33a ("[W]e affirm the district court's grant of summary judgment on Counts I-IV, holding that the Agreements *were not violative of Section 1 of the Sherman Act* . . . .") (emphasis added). Counts I-IV of the complaint include all of the reverse payment claims, including claims for injunctive relief under federal law (Count I) and state law (Count III). Just as in *Michigan v. Long*, 463 U.S. 1032, 1040-41 (1983), it is clear at a minimum that the Court of Appeals' "interpretation of state law has been influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes of Fort Berthold Reservation v. World Engineering, P.C.*, 467 U.S. 138, 152 (1984). It is clearly appropriate for this Court to grant certiorari to correct misapprehensions, such as those unambiguously expressed in the Federal Circuit's opinion, as to what type of conduct is unlawful under the Sherman Act.

Finally, there are federal injunctive and damage claims in the companion case presently pending in the Second Circuit [2d Cir. Nos. 05-2851 & 05-2852], and both appeals stem originally from the same district court opinion. To facilitate comprehensive review of the entire decision of the district court on reverse payment issues, it would be most appropriate to defer ruling on this petition for certiorari until a petition is filed by the parties in the parallel portion of the case that is on appeal in the Second Circuit, and to consider both petitions for

certiorari together. There were no such parallel "direct purchaser" claims under federal antitrust law in the *Tamoxifen* case. The Solicitor General's brief in *Tamoxifen* sheds no light on what the recommendation of the Solicitor General would have been, with regard to the petition for certiorari in *Tamoxifen*, if comparable parallel federal damage claims had been present in that case.

I. The Standard Adopted By Decisions Below and *Tamoxifen* Conflicts with Standards Articulated by Other Circuits, the Federal Trade Commission and Scholarly Commentators.

Under the majority opinion in *Tamoxifen*, an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation cannot violate the antitrust laws unless the patent litigation was a fraud, sham or otherwise baseless, or the settlement agreement imposes restrictions on the alleged infringer that extend beyond the scope of the challenged patent. *Tamoxifen*, 466 F.3d at 208-09. The Federal Circuit agrees that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." Pet. App. 24a. Pharmaceutical reverse payment agreements are therefore beyond the reach of antitrust scrutiny, even if, as here, the patent holder makes enormous payments to the alleged infringer in exchange for the latter's promise to abandon the patent challenge and its efforts to launch a generic product.

The *Tamoxifen* majority recognized that such *per se* legality shields questionable settlements involving

"fatally weak" patents, but concluded that the policy favoring settlement is so strong that it trumps antitrust concerns. *Tamoxifen*, 466 F.3d at 211 ("So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved."). As the Solicitor General has recognized, however, the general preference for settlements must be tempered when settlements have important adverse consequences on third-parties. *See* US Brief in *Tamoxifen* at 9 ("Although public policy wisely encourages settlements of legal disputes, it does not follow that all settlements are consistent with the antitrust laws.") (citation and quotation marks omitted).

The Sixth and Eleventh circuits have reached different conclusions. In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Sixth Circuit upheld the trial court's summary judgment ruling that a reverse payment agreement was *per se* illegal, *i.e.*, *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 683 (E.D. Mich. 2000). "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." 332 F.3d at 908. The substantial reverse payment made by the patent holder to the patent challenger was the driving force in the Sixth Circuit's reasoning. "It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors *by paying the only potential*

competitor $40 million per year to stay out of the market." Id. (emphasis added). The Sixth Circuit's decision is irreconcilable with the decisions below, which render issues such as the size of any reverse payment made to the patent challenger legally irrelevant. Indeed, the Federal Circuit has expressly disagreed with the Sixth Circuit's approach. Pet. App. 21a ("To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payment, we respectfully disagree.").

Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003) reversed a trial court ruling that a reverse payment agreement was *per se* illegal. The Eleventh Circuit held that because the "exclusionary power" of the patent needed to be considered, a rule of *per se* liability would be inappropriate "when no court had declared [the brand manufacturer's] patent invalid or unenforceable at the time of the Agreements." *Id.* at 1306 & n.18. Thus, the Eleventh Circuit has also expressly disagreed with the Sixth Circuit.[9] *Valley Drug*

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9. *See Valley Drug*, 344 F.3d at 311 n.26 ("To the extent that the Sixth Circuit [in *Cardizem CD*] suggests that a settlement of patent litigation was a per se violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, *we respectfully disagree*. We believe that the potential exclusionary power of the patent must first be considered.") (emphasis added); *accord Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006). *See also In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp.2d 1279, 1315 n.36 (S.D. Fla. 2005) ("The Eleventh Circuit [in *Valley Drug*] disagreed with the (Cont'd)

held that a fair analysis of the "exclusionary power" of the patent should include such factors as "what lost profits [the brand-name manufacturer] expected from generic competition or what profits [the generics] expected to gain from entry." 344 F.3d at 1310. This inquiry is necessary because "the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid." *Id.* at 1310 n.22. These elements of the *Valley Drug* opinion are irreconcilable with the decisions below and *Tamoxifen*.[10]

Hatch-Waxman Act reverse payment agreements have also been a "hot button" issue in antitrust scholarship for years. Academic literature is largely divided between "rule of reason" proponents, on the one hand, and *per se* illegality proponents on the other. Until *Tamoxifen*, no one had argued for *per se* legality, as the

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Sixth Circuit's approach in *Cardizem*, because that Court did not conduct an analysis of the exclusionary potential of the patent and also placed considerable reliance on the size of the exit payments.").

10. The Eleventh Circuit revisited these issues in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), but made clear that it continues to adhere to *Valley Drug*. *Id.* at 1065 ("We are bound by our decision in *Valley Drug*."). The *Schering* opinion also states that although the mere existence of a reverse payment is insufficient to establish unlawfulness, "[t]his alone underscores *the need to evaluate the strength of the patent*." *Id.* (emphasis added).

dissent there points out. *Tamoxifen*, 466 F.3d at 227-28 (Pooler, J., dissenting).[11] One of the foremost antitrust commentators has expressed the frank view that the district court's reasoning below (in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005)) just "doesn't work under Hatch-Waxman." Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *IP and Antitrust*, § 7.4 at 7-37 (2007 Supp.); *see also* Hemphill, 81 N.Y.U. L. Rev. at 1582-85 (addressing the *Tamoxifen* court's misunderstanding of the exclusivity period incentive).

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11. Some academic scholars have written that reverse payment settlements of Hatch-Waxman patent litigation with large payoffs to the alleged infringer should be presumptively anti-competitive. *See* C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *IP and Antitrust*, § 7.4e2 at 7-36 to 41 (2009 Supp.); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003); Jeremy Bulow, *The Gaming of Pharmaceutical Patents, in 4 Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* Competition Policy Center Working Paper 05-054 (2005), *available at* http://repositories.cblib.org/iber/cpc/CPC05-54/. Others have argued for application of the rule of reason, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491, 534-38 (2002), or for per se illegality. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003).

II. Recent Decisions have Undermined FTC Enforcement Efforts that had virtually Eliminated Pharmaceutical Exclusion Payments

Recent decisions, including the decisions below, have encouraged pharmaceutical companies to collude rather than compete and have undermined FTC enforcement of competition law. Prior to the *Schering* and *Tamoxifen* decisions, FTC enforcement actions[12] and private antitrust litigation[13] had virtually eliminated reverse payment settlements in Hatch-Waxman patent litigation. Section 1112 of the 2003 Medicare Amendments, signed by President Bush on December 8, 2003, requires the submission of pharmaceutical agreements to the FTC and Department of Justice. Congress passed this law to "re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand manufacturers." Brief for Henry A. Waxman as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026 (dated Sept. 30, 2005) at 10.

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12. *See, e.g., In the matter of Hoechst Marion Roussel, Inc., et al.*, No. 9293 Decision and Order (FTC May 8, 2001) (regarding Cardizem CD), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm; *In the matter of Abbott Laboratories, et al.*, No. C-3945, Decision and Order (FTC May 22, 2000) (regarding Hytrin), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. Most recently, the FTC and the State of California have challenged a pay-for-delay agreement in *FTC v. Watson Pharm., Inc.*, CV No. 09-00598 (C.D. Cal.) (complaint filed Jan. 29, 2009).

13. *See, e.g. In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508 (E.D. Mich. 2003), *aff'd in part and dismissed on other grounds*, 391 F.3d 812 (6th Cir. 2004).

For fiscal year 2004, none of the fourteen reported agreements between brand and generic manufacturers contained a payment from the brand to the generic accompanied by deferred generic entry.[14] *http://www.ftc.gov/oos/2005/1/050107medicareactrpt.pdf)* In other words, the parties to Hatch-Waxman patent litigation found ways to settle that did not require paying-off the generic manufacturer. For fiscal 2005, there were sixteen settlements and three included payments to the generic companies to defer market entry.[15] The Eleventh Circuit decision in *Schering*, issued midway through the fiscal year, had revived the practice.

The FTC reports for fiscal years 2006 and 2007 found dramatic increases in exclusion payments.[16] For

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14. Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by The Bureau of Competition* (Jan. 7, 2005), *available at* http://www.ftc.gov/opa/2005/01/drugsettlement.htm.

15. Federal Trade Commission, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2005: A Report by the Bureau of Competition* (April 24, 2006), *available at*: http://www.ftc.gov/opa/2006/04/drugsettlements.shtm.

16. *See* Federal Trade Commission, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2006: A Report by the Bureau of Competition* (Jan. 17, 2007) ("FY 2006

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FY 2006, fourteen of the twenty-eight final settlements (50%) included provisions in which the generic manufacturer received some form of compensation from the manufacturer of the brand product at issue in the litigation and restrictions on the generic manufacturer's ability to enter with its product. *See* FY 2006 Report at 4 ("Each of the agreements involved a product with 2005 U.S. annual sales exceeding $125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than $450 million."). For FY 2007, fourteen of the thirty-three final settlements (42%) included such provisions. FY 2007 Report at 3. "The vast majority of these agreements involved first filer generic companies (79%)." *Id.* at 2.

There can be no doubt that the *Schering* and *Tamoxifen* decisions are largely (if not exclusively) responsible for the disturbing increase in anticompetitive settlements. *See* Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006) at 7-8[17] ("If the *Schering* and *Tamoxifen* decisions are not reversed — that is, if branded firms are empowered by

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Report"), *available at*: http://www.ftc.gov/opa/2007/01/drugsettlements.htm; Federal Trade Commission, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2007: A Report by the Bureau of Competition* (May 2008) ("FY 2007 Report"), *available at*: http://www.ftc.gov/opa/2008/05/drug.shtm.

17. *Available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

the courts to pay the generic more than it would have made by competing — these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration.") & 13-14 ("[J]ust before *Schering* and *Tamoxifen*, there were no [reverse] payments; just after them, this appears to be the new way to do business."). Those decisions, followed by the Federal Circuit in this case, fostered a new era for reverse payment agreements that keep lower-priced generic drugs *out* of consumers' hands, contrary to the express purposes of the Hatch-Waxman Act. Judge Pooler's dissent in *Tamoxifen* — which characterized the majority's "tacit assumption that the settling parties will not act to injure the consumer or competition" as "panglossian" (466 F.3d at 228 n. 5) — has proved prophetic.

The FTC continues to challenge reverse payments, but it has conspicuously avoided bringing such cases in district courts within the Second and Eleventh Circuits and its own administrative proceedings (wherein an aggrieved defendant can choose the Court of Appeals). *See, e.g., Federal Trade Commission v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.) (concerning reverse payment agreement delaying generic versions of Provigil); Federal Trade *Commission v. Watson Pharmaceuticals, Inc.*, No. 09-cv-598 (C.D. Cal.) (concerning reverse payment agreement delaying generic versions of AngroGel).

III. This Case Presents a Straightforward Pay-for Delay Agreement Without Materially Unique Fact Issues.

This case is a particularly attractive vehicle for addressing conflicting circuit court standards because it involves an unambiguous pay-for-delay deal that was entered before increased scrutiny from the FTC caused pharmaceutical companies to conceal exclusion payments in increasingly complex arrangements. As recently explained in testimony before Congress, reverse payment settlements have occurred in two distinct waves.[18] The first wave began in 1993 and ended in 2000, after the FTC made clear its opposition to pay-for-delay settlements. The second wave began in 2005, in "direct response to the failure of federal courts [in *Schering-Plough* and *Tamoxifen*] to recognize and resolve the pay-for-delay issue." Hemphill Testimony at 8. "That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay." *Id.*

> In the earliest settlements, such as tamoxifen, BuSpar, Zantac and ***Cipro*** settlements, payment *was a relatively straightforward*

18. Testimony of C. Scott Hemphill, Associate Professor, Columbia Law School, House Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007 (May 2, 2007) ("Hemphill Testimony") at 7; *available at:* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf.

> *affair*. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. Modern settlements also entail payment for delay, *but the parties avoid a straight conveyance of cash*, preferring instead to employ a variety of alternative forms of payment.

Id. at 8-9 (emphasis added).

More recent agreements often rely upon complicated side deals as "means to smuggle compensation to the generic firm." *Id.* at 9; *see, e.g.*, Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273, 2006 WL 1358441 (dated May 2006) at 12-13 (recommending denial of certiorari because, *inter alia*, "[t]he court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's product.") (citation to record omitted). Indeed, in *Schering* the Solicitor General pointed to eventual review of the *Ciprofloxacin* litigation as grounds to deny plenary review there. *See id.* at 16.

Accordingly, the facts of this case and the rulings below will allow the Court to address the antitrust implications of a straightforward, pay-for-delay agreement. Absent guidance by this Court, the conflicting circuit court standards leave everyone — the pharmaceutical industry, antitrust regulators, and the purchasers and consumers of pharmaceuticals (*i.e.*, those who ultimately must pay the bill) — in a quandary.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED OCTOBER 15, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1097

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION; ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN, MARK ASTON, BOARD OF TRUSTEES OF THE UNITED FOOD & COMMERCIAL WORKERS OF ARIZONA HEALTH AND WELFARE FUND, ADELE BRODY, MICHELLE CROSS, DONNA FRANCK, KRISTINE GADDIS, DAVID GREEN, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, JOHN H. IRONS, LOCAL 1199 NATIONAL BENEFIT FUND FOR HEALTH AND HUMAN SERVICES EMPLOYEES, MARIA LOCURTO, CAROLINE M. LOESCH, KIMBERLY MCCULLAR, LINDA K. MCINTYRE, MECHANICAL CONTRACTORS-UA LOCAL 119 WELFARE PLAN, THERESA MEYERS, PATRICIA NELSON, FRANCES NORRIS, PAPER, ALLIED-INDUSTRIAL, CHEMICAL AND ENERGY WORKERS INTERNATIONAL UNION, AFL-CIO, CLC, MARY ANN SCOTT, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, MAURICE STEWART, ANN STUART, UNITED FOOD & COMMERCIAL WORKERS AND

Appendix A

PARTICIPATING FOOD INDUSTRY EMPLOYERS TRI-STATE HEALTH & WELFARE FUND, and VISTAHEALTHPLAN, INC.,

Plaintiffs-Appellants,

v.

BAYER AG and BAYER CORP.,

Defendants-Appellees,

and

HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (doing business as Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,

Defendants-Appellees,

and

BARR LABORATORIES, INC.,

Defendant-Appellee.

October 15, 2008, Decided

Before SCHALL and PROST, Circuit Judges, and WARD, District Judge.*

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* Honorable T. John Ward, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

Appendix A

PROST, *Circuit Judge.*

This case under the Hatch-Waxman Act presents the issue of whether a settlement agreement between a patent holder and a generic manufacturer violates the antitrust laws. The agreements here involve a reverse payment from the patent holder to the generic manufacturer, but do not implicate the 180-day exclusivity period. Indirect purchasers of Cipro and several advocacy groups ("appellants") appeal the grant of summary judgment of their federal antitrust claims and dismissal of their state antitrust claims against the patent holders and brand-name manufacturers, Bayer AG and Bayer Corp. (collectively "Bayer"), and the generic manufacturers, Barr Labs., Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), The Rugby Group, Inc. ("Rugby"), and Watson Pharmaceuticals, Inc. ("Watson") (collectively "generic defendants"). The United States District Court for the Eastern District of New York granted Bayer's and the generic defendants' motion for summary judgment, holding that any anti-competitive effects caused by the settlement agreements between Bayer and the generic defendants were within the exclusionary zone of the patent, and thus could not be redressed by federal antitrust law. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F.Supp.2d 514 (E.D.N.Y.2005) ("*Cipro II*"). The court further granted Bayer's motion to dismiss the state antitrust claims. For the reasons set forth below, we affirm.

Appendix A

I

A

Bayer is the owner of U.S. Patent No. 4,670,444 ("the '444 patent"). The patent relates to certain quinoline- and napthyridine-carboxylic acid compounds with antibacterial properties and methods of administering the compounds to combat bacterial illnesses. '444 patent, col.1 ll.13-17, col.2 ll.28-32, claims 1, 21. More particularly, the patent is directed to ciprofloxacin hydrochloride, the compound that is the active ingredient in Cipro® ("Cipro"). *Id.*, claim 12. The patent issued on June 2, 1987, and Bayer's predecessor obtained approval from the Food and Drug Administration ("FDA") to market Cipro in October 1987. The FDA granted Bayer an additional six-month period of marketing exclusivity (pediatric exclusivity) following the expiration of the patent on December 9, 2003.

In October 1991, Barr filed an abbreviated new drug application ("ANDA") for a generic version of Cipro. The ANDA included a Paragraph IV certification[1] indicating that Barr sought to market its generic drug before expiration of the '444 patent on the grounds that the patent was invalid and unenforceable.[2] Specifically, Barr

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1. The filer of a Paragraph IV ANDA certifies that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

2. Barr did not certify that its product did not infringe the '444 patent.

asserted that the patent was invalid based on obviousness under 35 U.S.C. § 103 and obviousness type double patenting under 35 U.S.C. § 101, and unenforceable due to inequitable conduct. Under the Hatch-Waxman Act, the first filer of a Paragraph IV ANDA is automatically entitled to a 180-day period of market exclusivity, which, in the version of the Act in effect at the time, begins to run either on the date that the first ANDA filer begins to market its drug or on the date of a final court decision finding the patent to be invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(4)(B)(iv) (1988). Thus, as the first Paragraph IV ANDA filer, Barr was entitled to the 180-day exclusivity period.

On January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York. Barr answered and counterclaimed for a declaratory judgment that the '444 patent is invalid and unenforceable and that its generic ciprofloxacin would not infringe the '444 patent. In 1996, Rugby (a subsidiary of HMR) and Barr entered into the "Litigation Funding Agreement," in which Rugby agreed to help Barr fund its litigation against Bayer in exchange for half of any profits realized from Barr's sale of ciprofloxacin. Also, in 1996, Bayer entered into settlement discussions with HMR and Barr.

Just before trial, Bayer, Barr, HMR, and Rugby entered into the following agreements (collectively "the Agreements"): (1) the "Barr Settlement Agreement" between Bayer and Barr; (2) the "HMR/Rugby

Settlement Agreement" among Bayer, HMR, and Rugby; (3) the "Apotex Settlement Agreement" among Bayer, Bernard Sherman (Barr's principal shareholder), and Apotex (another company controlled by Sherman); and (4) the "Cipro Supply Agreement" among Bayer, Barr, and HMR.[3]

The first three agreements provided that Barr, HMR, Rugby, Apotex, and Bernard Sherman would not challenge the validity or enforceability of the '444 patent. Pursuant to the Barr Settlement Agreement, Barr agreed to convert its Paragraph IV ANDA to a Paragraph III ANDA, thus certifying that it would not market its generic version of Cipro until after the '444 patent expired.[4] *See* 21 U.S.C. § 355(j)(2)(A)(vii) (III). In exchange, Bayer agreed to make a settlement payment to Barr of $49.1 million.

Under the Cipro Supply Agreement, Bayer agreed to either supply Barr with Cipro for resale or make

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3. Notably, the Agreements were entered into before the 2003 amendments to the Hatch-Waxman Act, requiring a patent holder and a first Paragraph IV ANDA filer who settle their patent litigation to file their agreement with the Federal Trade Commission and Department of Justice for review, and if the agreement is found to violate the antitrust laws, the first ANDA filer loses its right to the 180-day exclusivity period. Pub.L. No. 108-173, § 1112; *see* 21 U.S.C. § 355(j)(5)(D)(i)(V).

4. Barr, however, preserved the option to reamend its ANDA to a Paragraph IV certification—in order to reclaim the 180-day exclusivity period—in the event a court declared the '444 patent to be invalid or unenforceable.

quarterly payments (referred to as "reverse payments" or "exclusion payments") to Barr until December 31, 2003.[5] In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. Beginning at least six months before the '444 patent expired, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. Bayer and Barr then entered into a consent judgment, whereby Barr affirmed the validity and enforceability of the '444 patent and admitted infringement.

On July 25, 1997, Bayer filed for reexamination. Bayer cancelled and amended certain claims, and the validity of the remaining claims of the '444 patent was reaffirmed by the Patent and Trademark Office ("PTO") in the reexamination certificate. In particular, the patentability of claim 12, directed to ciprofloxacin hydrochloride, was confirmed.

Thereafter, four other companies—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs for a generic version of Cipro. Bayer sued each of them for infringement of the reexamined '444 patent. The issue of inequitable conduct was not adjudicated in any of the actions. Bayer defeated Schein and Mylan's challenges to the validity of the '444 patent on summary judgment. *Bayer AG v. Schein Pharm., Inc.*, 129 F.Supp.2d 705

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5. Added to the $49.1 million initial payment, the payments from Bayer to Barr totaled $398.1 million. Barr shared the payments equally with HMR.

(D.N.J.2001), *aff'd*, 301 F.3d 1306 (Fed.Cir.2002). The validity of the '444 patent was upheld after a bench trial in the *Carlsbad* case. *Bayer AG v. Carlsbad Tech., Inc.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002). The Ranbaxy case was dismissed after Ranbaxy withdrew its Paragraph IV certification.

B

In 2000 and 2001, direct and indirect purchasers of Cipro and advocacy groups filed several antitrust actions in federal courts challenging the Agreements. The cases were consolidated in the Eastern District of New York pursuant to 28 U.S.C. § 1407. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001). Thereafter, the plaintiffs filed a consolidated complaint containing Counts I-IV, which alleged that the Agreements constituted an illegal market allocation in violation of the prohibition on contracts in restraint of trade contained in sections 1 and 2 of the Sherman Act and in violation of various state antitrust and consumer protection laws.

On May 20, 2003, the district court denied the plaintiffs' motion for partial summary judgment that the Agreements were per se unlawful under the Sherman Act and under the state antitrust and consumer protection laws. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188 (E.D.N.Y.2003) ("*Cipro I*").

The plaintiffs then amended their complaint to add Count V, a state law *Walker Process* type[6] antitrust claim, alleging that Bayer unlawfully monopolized the ciprofloxacin market in violation of state antitrust laws by enforcing a patent obtained by fraud. Specifically, they alleged that Bayer violated state antitrust and/or consumer protection laws through fraud on the PTO and sham litigation in enforcing the '444 patent against Barr.

The parties filed cross-motions for summary judgment regarding whether the Agreements had anti-competitive effects under section 1 of the Sherman Act. The district court denied the plaintiffs' motion and granted Bayer's and the generic defendants' motion. *Cipro II*, 363 F.Supp.2d at 548. Employing a rule of reason analysis, the district court first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. *Id.* at 520-23. The court then determined that any adverse effects on competition stemming from the Agreements were within the exclusionary zone of the '444 patent, and hence could not be redressed by antitrust law. *Id.* at 523-40. In so concluding, the court considered recent decisions by the Second Circuit, as well as other regional circuits, and rejected the plaintiffs' argument that the exclusionary

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6. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court held that the enforcement of a patent procured by fraud on the patent office may be a violation of the Sherman Act provided that the other elements necessary to a Sherman Act claim are present. *Id.* at 177, 86 S.Ct. 347. Here, however, the plaintiffs alleged a violation of state antitrust laws.

power of the patent, for the purpose of the anti-competitive effects analysis, should be tempered by the patent's potential invalidity. *Id.* Given the absence of evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition beyond the scope of the patent, the court concluded that the plaintiffs had failed to show that the Agreements had any anti-competitive effects on the market for ciprofloxacin beyond that permitted under the patent. *Id.* at 540. Thus, the court found it unnecessary to address the second and third steps of the rule of reason analysis. *Id.* at 541.

Bayer also filed a motion to dismiss Count V as preempted by federal patent law and barred by the statute of limitations. The district court agreed that Count V is preempted by federal patent law because the plaintiffs alleged no theory for a *Walker Process* claim or sham litigation claim that does not depend on a showing of misconduct before the PTO. *Id.* at 542-46. The court noted that Count V does not allege any misconduct other than misconduct before the PTO, i.e., there is no allegation of marketplace misconduct. *Id.* Thus, the court concluded that Count V rests entirely on patent law.[7] *Id.* The court also reasoned that Bayer's success in its litigation against Schein, Mylan and Carlsbad foreclosed any argument that its lawsuits were shams. *Id.* at 547. Because the court granted Bayer's motion to dismiss on preemption grounds, it did not

7. The court further noted that there was a serious question whether the indirect purchasers even had standing to assert a *Walker Process* claim. *Id.* at 547.

reach whether Count V was barred by the statute of limitations. *Id.* at 547-48.

This appeal followed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).[8]

II

This court reviews the district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed.Cir.2008); *U.S. Phillips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1374 (Fed.Cir.2007). Summary judgment is appropriate where, after drawing all reasonable inferences in favor of the non-movant, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *Rubens v. Mason*, 527 F.3d 252, 254 (2d Cir.2008).

This court also reviews the district court's grant or denial of a motion to dismiss de novo. *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1368 (Fed.Cir.2007); *Univ. of W. Va. Bd. of Trs. v. Van Voorhies*, 278 F.3d 1288, 1295 (Fed.Cir.2002). Whether federal patent law

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8. Count V is subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a) because the determination of fraud before the PTO necessarily involves a substantial question of patent law. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988).

preempts a state law claim is a question of law which we review de novo. *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed.Cir.2005).

III

The appellants allege that the district court erred in its determination that the Agreements did not constitute an unreasonable restraint of trade in violation of section 1 of the Sherman Act, and in its grant of Bayer's and the generic defendants' motions for summary judgment on Counts I-IV, as follows: (1) by not finding the Agreements to be per se unlawful, or at least applying a proper rule of reason analysis; (2) by finding the Agreements to be lawful because they fell within the "exclusionary zone" of the '444 patent; (3) by not considering the law of the regional circuits and government agencies in evaluating the Agreements; (4) by failing to appreciate the effects of the Agreements on other generic manufacturers; and (5) by not considering evidence showing that the Agreements preserved Barr's claim to the 180-day exclusivity period. We address each asserted error in turn.

A

According to the appellants, the Agreements allowed Bayer to exclude a horizontal competitor from the market not by enforcing its rights as a patentee, but instead by ceasing to enforce its rights and paying the competitor $398 million. The appellants contend that the district court should have concluded that the

Agreements were per se unlawful or should have applied a proper rule of reason analysis. At a minimum, the appellants assert, the court should not have resolved the case on summary judgment, but instead should have presented it to a fact-finder to determine whether the Agreements constituted an unreasonable restraint on trade.[9]

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although by its terms, the Act prohibits any "restraint of trade," the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997). Courts will presumptively apply a "rule of reason" analysis to determine whether an agreement imposes an unreasonable restraint on competition. *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5, 126 S.Ct. 1276, 164 L.Ed.2d 1 (2006). Only agreements that have a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" are deemed to be per se unlawful under the Sherman Act. *State Oil*, 522

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9. Specifically, the appellants contend that there are genuine issues of material fact relating to whether the defendants received far more under the Agreements then they could have had Barr won the litigation against Bayer, invalidated the '444 patent, and entered the market. Further, the appellants aver that the court needs to assess the apparent strength of the patent at the time of the Agreements.

U.S. at 10, 118 S.Ct. 275. A finding of per se unlawfulness "is appropriate '[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.' " *Id.* (quoting *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 344, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982)). The Supreme Court has expressed reluctance to adopt per se rules where the economic impact is not immediately obvious. *Id.*

Since there was no basis for the district court to confidently predict that the Agreements at issue here would be found to be unlawful under a rule of reason analysis, we find no error by the court in declining to find them to be per se unlawful. Instead, the court properly went through a rule of reason analysis to determine whether the Agreements were in fact an unreasonable restraint of trade.

Under the law of the Second Circuit, the rule of reason analysis is a three-step process:

> First, the plaintiff bears the initial burden of showing that the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an

alternative means that is less restrictive of competition.

Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir.1997) (citations and internal quotations omitted). Typically, the starting point is to define the relevant market, *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 495-96 (2d Cir.2004), and to determine whether the defendants possess market power in the relevant market. *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir.2003). Although the precise role that market power plays in the rule of reason analysis is unclear, it may be a highly relevant factor. *Id.* at 238 n. 4; *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 546 (2d Cir.1993).

Contrary to the contentions of the appellants, the court did undertake a full rule of reason analysis. It first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. *Cipro II*, 363 F.Supp.2d at 523. It then determined that there was no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the "exclusionary zone" of the patent. *Id.* at 540. Thus, the court concluded that the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent. *Id.* Because the court concluded that the plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it did not find it necessary to consider the second or third steps of the analysis. *Id.* at 541.

The appellants assert, however, that the district court erred in concluding that the Agreements were within the "exclusionary zone" of the '444 patent, in essence treating them as per se legal. According to the appellants, the patentee's right to exclude competition is not defined by the facial scope of the patent, but rather is limited to the right to exclude others from profiting from the patented invention. Under the Agreements, the appellants argue, Bayer is seeking not simply to enforce its patent rights, but to insulate itself from competition and avoid the risk that the patent is held invalid.

The district court did not treat the Agreements as per se legal. Rather, the court simply recognized that any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law. *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485, 47 S.Ct. 192, 71 L.Ed. 362 (1926); *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91, 22 S.Ct. 747, 46 L.Ed. 1058 (1902); *see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 201-02 (2d Cir.2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir.2003); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C.Cir.1981). This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of "the right to exclude others from making, using, offering for sale, or selling the invention. . . ." 35 U.S.C. § 154(a)(1); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d

696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). Thus, "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381 (1945). The district court appreciated this underlying tension between the antitrust laws and the patent laws when it compared the anti-competitive effects of the Agreements with the "zone of exclusion" provided by the claims of the patent. *See In re Tamoxifen*, 466 F.3d at 201-02; *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir.2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir.2005); *Valley Drug*, 344 F.3d at 1312. Because the court found no anti-competitive effects outside the exclusionary zone of the patent, it concluded that the Agreements were not violative of section 1 of the Sherman Act. *Cipro II*, 363 F.Supp.2d at 540-41.

We find no error in the court's analysis. Pursuant to the Agreements, the generic defendants agreed not to market a generic version of Cipro until the '444 patent expired[10] and not to challenge the validity of the '444 patent, and Bayer agreed to make payments and optionally supply Cipro for resale. Thus, the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee. Furthermore, there is a

10. Under the Cipro Supply Agreement, however, Barr was allowed to sell a competing ciprofloxacin product six months before the '444 patent expired.

long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation. *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed.Cir.2001); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 477 (Fed.Cir.1991). Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.[11] *Standard Oil Co. v. United States*, 283 U.S. 163, 171 & n. 5, 51 S.Ct. 421, 75 L.Ed. 926 (1931).

We disagree with the appellants that the fact that the generic defendants agreed not to challenge the validity of the '444 patent renders the Agreements violative of the antitrust laws. According to the appellants, there is a vital public interest in patent validity challenges to ensure that consumers are not burdened by unwarranted patent monopolies. Appellants assert that Congress underscored this public interest by providing in 35 U.S.C. § 282 that an issued patent carries only a rebuttable presumption of validity, which can be challenged in court. In fact, appellants argue, at the preliminary injunction stage, the patentee has the burden of establishing the likelihood of success on the merits of the patent's validity. Furthermore, the appellants contend, in the Hatch-Waxman Act, Congress

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11. Indeed, a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed. *Schering-Plough*, 402 F.3d at 1074; *see infra* pp. 23-24.

provided the incentive of a 180-day exclusivity period to the first generic manufacturer to challenge a patent.

Settlements in patent cases, however, frequently provide that the alleged infringer will not challenge the validity of the patent. *See, e.g., Flex-Foot*, 238 F.3d at 1367, 1370; *Diversey Lever, Inc. v. Ecolab, Inc.*, 191 F.3d 1350, 1351 (Fed.Cir.1999); *Interspiro USA, Inc. v. Figgie Int'l, Inc.*, 18 F.3d 927, 932 (Fed.Cir.1994). Thus, the mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation. Indeed, there is no evidence that the Agreements prevented challenges by other generic drug manufacturers to the validity of the '444 patent. In fact, four other generic manufacturers—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs and initiated challenges of the validity of the patent.

C

The appellants urge this court to consider the legal standards applied by the regional circuits and government agencies in addressing Agreements involving exclusion payments in the context of the Hatch-Waxman Act, all of which, they assert, encompass greater antitrust scrutiny than the standard adopted by the district court. In particular, the appellants point to the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir.2003), upholding a summary judgment ruling by the district court that a reverse payment agreement is per se illegal. Further,

the appellants assert that although the Eleventh Circuit in *Valley Drug* reversed the district court's ruling of per se illegality, it provided a more extensive analytical framework within which to review the settlement agreements on remand. And, in *Schering-Plough*, the appellants assert the Eleventh Circuit adhered to the standard in *Valley Drug* and recognized the need to evaluate the strength of the patent in determining whether reverse payments are unlawful. The appellants contend that the Federal Trade Commission ("FTC") advocates a rule of reason inquiry focusing on the amount of the payment and several other factors, although not requiring consideration of the validity of the patent. Finally, the appellants note that the Solicitor General has suggested that a reverse payment should be evaluated using a rule of reason approach and that "the strength of the patent as it appeared at the time at which the parties settled" should be considered in the analysis, citing Brief for the United States as Amicus Curiae at *12, *Joblove v. Barr Labs.*, __ U.S. __, 127 S.Ct. 3001, 168 L.Ed.2d 726 (2007) (No. 06-830), 2007 WL 1511527. According to the appellants, only the Second Circuit in *In re Tamoxifen*, has concluded that a settlement between a patent holder and an alleged infringer in Hatch-Waxman litigation does not violate the antitrust laws provided the litigation is not baseless, although it recognized that such an approach shields settlement agreements involving "fatally weak" patents. Therefore, the appellants assert, the district court's treatment of the Agreements here was not in line with that of the other circuits, the FTC, and the Solicitor General, and we should reject the district court's approach in lieu of those other standards.

We find, however, the district court's analysis to be sound. As noted above, the district court applied a rule of reason analysis in assessing the lawfulness of the Agreements. In that analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent. The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch-Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a per se violation of the antitrust laws in *In re Cardizem*, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. *In re Cardizem*, 332 F.3d at 907. Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. *Id.* at 908 n. 13. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent. *See* Brief for the United States, 2007 WL 1511527 at *16 n. 7 (No. 06-830); Brief for the United States as Amicus Curiae at *17, *FTC v. Schering-Plough Corp.*, (No. 05-273), 2006 WL 1358441. To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.

Appendix A

The Eleventh Circuit in *Valley Drug* reversed a finding by the district court that settlement agreements constituted a per se violation of the antitrust laws because the court failed to consider the exclusionary power of the patent in its antitrust analysis. 344 F.3d at 1306, 1312. Although it rejected the court's condemnation of the agreements as a per se antitrust violation, it did not advocate application of a rule of reason analysis, finding such an analysis to be inappropriate given that the anticompetitive effects of the exclusionary zone of a patent are not subject to debate. *Id.* at 1312 n. 27. In so holding, it emphasized that the subsequent declaration of invalidity did not render the patent's potential exclusionary effects irrelevant to the antitrust analysis. *Id.* at 1309. It did leave open the possibility, however, that an antitrust violation could be found in the extreme situation where there was evidence of fraud on the PTO or sham litigation. *Id.* at 1309 & n. 21. On remand, it ordered the district court to consider the exclusionary potential of the patent, the extent to which provisions of the settlement agreement exceeded the scope of the patent, and the anticompetitive effects of those provisions. *Id.* at 1312.

This approach was followed by the Eleventh Circuit in *Schering-Plough* and *Andrx Pharmaceuticals* and by the Second Circuit in *In re Tamoxifen*. *In re Tamoxifen*, 466 F.3d at 212; *Andrx Pharms.*, 421 F.3d at 1235; *Schering-Plough*, 402 F.3d at 1066. In *Schering-Plough*, the Eleventh Circuit set aside the decision by the FTC that the settlement agreements constituted

an unreasonable restraint of trade. 402 F.3d at 1058. It noted that there was no evidence that the patent was invalid or that the litigation was a sham, and thus the proper analysis was whether the agreements restricted competition beyond the exclusionary effects of the patent. *Id.* at 1068. After reviewing the terms of the settlement agreements, it found that they were within the exclusionary zone of the patent and therefore protected by patent law. *Id.* at 1072. The Second Circuit, in *In re Tamoxifen*, similarly concluded that the validity of the patent need not be considered in the analysis of whether the settlement agreement violates the antitrust laws unless the infringement suit was objectively baseless. 466 F.3d at 213. In that case, the patent holder settled with the generic manufacturer after losing on validity before the district court and while on appeal to this court. *Id.* at 193. In so holding, the Second Circuit recognized that alleged Sherman Act violations are generally evaluated under a rule of reason analysis. *Id.* at 201 n. 13. It concluded that the presence of a reverse payment, or the size of a reverse payment, alone is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection. *Id.* at 212-13. Because the agreement did not extend to non-infringing products and did not create a bottleneck for other generic manufacturers, the court held that any anticompetitive effects were within the exclusionary power of the patent. *Id.* at 213-16.

We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are

within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies).

In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.[12] The FTC has also

12. Although certain statements by the Eleventh Circuit have been interpreted to mean that it advocated consideration of the validity of the patent, Brief for the United States at *16, *Joblove*, __ U.S. __, 127 S.Ct. 3001, 168 L.Ed.2d 726 (No. 06-830); Brief for the United States at *17-19, *Schering-Plough* 548 U.S. 919, 126 S.Ct. 2929, 165 L.Ed.2d 977 (No. 05-273), the district court correctly noted that the Eleventh Circuit did not consider or rely on evidence of patent invalidity in either *Valley Drug* or *Schering-Plough. Cipro II*, 363 F.Supp.2d at 525, 529.

rejected the application of a post hoc analysis of the validity of the patent as part of the antitrust analysis. In its decision that led to the Eleventh Circuit appeal in *Schering-Plough*, the FTC concluded that "it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." *In re Schering-Plough Corp.*, No. 9297, 2003 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003). However, on petition for writ of certiorari, the FTC criticized the Eleventh Circuit's approach to evaluating the exclusionary potential of the patent because it "ignore[d] the most salient factor that gives rise to patent litigation and settlements, the existence of *uncertainty* regarding whether a patent is valid or . . . infringed by particular products." Petitioner's Opening Brief at *15, *Schering-Plough*, (2006) (No. 05-273), 2005 WL 2105243. Similarly, here, the FTC argues that the district court erred by equating the exclusionary power of the patent with the scope of the patent claims without consideration of the uncertainty of patent validity. Corrected Br. of Amicus Curiae FTC in Supp. of Appellants 19. Apparently, the FTC, in recognizing the "probabilistic" nature of the patent interest, recommends that the "expected value" of the lawsuit at the time of the settlement be considered in the antitrust analysis. Petitioner's Opening Brief at *16, *Schering-Plough*, (No. 05-273), 2005 WL 2105243; Reply Brief for the Petitioner at *6, *Schering-Plough*, (No. 05-273), 2005 WL 2652617.

The Solicitor General advocates that an appropriate antitrust analysis "should take into account the relative likelihood of success of the parties' claims, viewed ex ante." Brief for the United States at *12, *Joblove*, (No. 06-830), 2007 WL 1511527; Brief for the United States at *11, *Schering-Plough*, (No. 05-273), 2005 WL 2105243. Practically, the Solicitor General proposes that, while the court need not conduct a full trial, it could conduct a limited evaluation of the merits of the patent claims. Brief for the United States at *13, *Joblove* (No. 06-830), 2007 WL 1511527; Brief for the United States at *11 n. 1, *Schering-Plough*, (No. 05-273), 2005 WL 2105243. While the expected value of the lawsuit (considered in the approach advocated by the FTC) should relate directly to the relative strength of the claim (considered in the approach advocated by the Solicitor General), the distinction between the approaches advocated by the FTC and the Solicitor General may lie in the fact that the expected value of the lawsuit depends on the subjective views of the parties as opposed to objective evidence of validity. *See* Brief for the United States at *12, *Schering-Plough*, (No. 05-273), 2005 WL 2105243.

We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with "the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980). A settlement is not unlawful if it serves to

protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention. *In re Tamoxifen*, 466 F.3d at 208-09. Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements. *Cipro II*, 363 F.Supp.2d at 531-32. As Judge Posner remarked, if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 992 (N.D.Ill.2003).

Accordingly, we find the analysis by the district court to be fully supported in law and to demonstrate that it was cognizant of the legal standards applied by the regional circuits and government agencies in addressing agreements involving exclusion payments in the context of the Hatch-Waxman Act.

D

The appellants next contend that the district court erred in reasoning that even though Bayer settled with Barr, other generic companies could still challenge the '444 patent and their incentive to challenge the patent would grow with the chance that the patent would be held invalid, rendering any anticompetitive effects of the

Agreements short-lived. According to the appellants, while that reasoning may make sense outside the Hatch-Waxman context, it does not apply under Hatch-Waxman, where they allege generic manufacturers are less motivated to initiate and vigorously challenge a patent. The appellants contend that the incentives are significantly reduced in the Hatch-Waxman context because any generic manufacturer that wishes to challenge the patent must first undertake the effort, time, and expense of filing a Paragraph IV ANDA. The appellants further assert that few generic manufacturers are capable of initiating such a challenge and any challenge would be significantly delayed. Thus, the appellants argue that the brand name manufacturer, by paying off the first Paragraph IV ANDA filer, can protect its monopoly from competition for years—particularly near the end of the patent term—even if its patent is "fatally weak." It is that delay in challenge by generic manufacturers that is emphasized by the appellants here, since there is no dispute that four other generic manufacturers ultimately challenged the validity of the '444 patent.

While we recognize that the Hatch-Waxman Act creates certain burdens for generic manufacturers, it also provides significant benefits. First, it streamlines the process of obtaining FDA approval to market a generic version of a drug without having to go through the rigorous new drug application ("NDA") process that the patent holder is required to do. *Compare* 21 U.S.C. § 355(j)(2)(A) with 355(b)(1). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S.Ct. 2683, 110

L.Ed.2d 605 (1990). Thus, the generic drug manufacturers can piggyback on the safety and efficacy studies conducted by the patent holder. Second, it allows the generic manufacturers to challenge the validity of a patent simply by filing a Paragraph IV ANDA. 21 U.S.C. § 355(j)(2)(A)(vii), (5)(C)(i); *see Eli Lilly*, 496 U.S. at 677, 110 S.Ct. 2683. Thus, as explained by the Eleventh Circuit, the Hatch-Waxman Act redistributes the relative risks between the patent holder and generic manufacturers, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. *Schering-Plough*, 402 F.3d at 1074. Thus, the district court reasonably concluded that the incentive to mount a challenge would increase with the chance that the patent would be held invalid. *Cipro II*, 363 F.Supp.2d at 534. Further, the district court noted that there was no evidence that the Agreements created a bottleneck preventing generic challenges to the '444 patent. *Id.* at 540. Indeed, the patent was subsequently challenged by four other generic manufacturers and was upheld as valid.

E

Finally, the appellants contend that the district court erred in not considering evidence showing that the Agreements preserved Barr's claim to the 180-day exclusivity period, which served the defendants' joint interest in protecting the Cipro monopoly from generic competition. According to the appellants, the district court refused to consider the evidence in *Cipro II*

because it had earlier denied the plaintiffs' motions for partial summary judgment in *Cipro I*. But, the appellants assert, the district court should have considered the evidence anew in *Cipro II*, because: (1) the plaintiffs were now the nonmoving parties and thus the evidence should have been considered in the light most favorable to the plaintiffs; and (2) at issue was whether the Agreements had an actual adverse effect on competition in the relevant market, whereas in *Cipro I* the issue was the per se illegality of the Agreements. The appellants aver that the evidence raised genuine issues of material fact regarding whether the Agreements preserved Barr's claim to the 180-day exclusivity period, delayed and deterred other generic manufacturers from entering the ciprofloxacin market, and thus had an actual adverse effect on competition.

Again, we find no error in the district court's analysis. In addressing whether the Agreements restrained competition outside the scope of the '444 patent, the court observed that the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated by Barr. *Cipro II*, 363 F.Supp.2d at 540. However, the court noted that that theory had already been addressed in *Cipro I*. Specifically, in *Cipro I*, the court determined that the Agreements did not create a "bottleneck" for future Paragraph IV ANDA filers because Barr had no right to the 180-day exclusivity period. 261 F.Supp.2d at 243. That was because at the time of the Agreements, the FDA regulation in effect conditioned the first Paragraph IV ANDA filer's right to the 180-day exclusivity period

on a "successful defense" of its Paragraph IV ANDA against the patent holder. *Id.; see* 21 C.F.R. § 314.107(c)(1) (1998), *revoked* 63 Fed.Reg. 59710, 59711 (Nov. 5, 1998). However, Barr acknowledged in the consent judgment both its infringement and the validity of the '444 patent, thereby ending the underlying litigation. *Cipro I*, 261 F.Supp.2d at 243. More importantly, as part of the Agreements, Barr converted its Paragraph IV ANDA to a Paragraph III ANDA. *Id.* Thus, the court concluded that Barr had failed to satisfy the successful defense requirement necessary to be eligible for the 180-day exclusivity period. *Id.*

We do not know what evidence the plaintiffs believe would have created a genuine issue of material fact had it been considered by the district court in *Cipro II*. There appears to be no dispute about the contents of the consent judgment and the Agreements, and there does not appear to be a dispute about what was contained in the FDA regulation that was in effect at the time. Although the appellants make much of the uncertainty in the law regarding the validity of the "successful defense" requirement,[13] we find no merit to that argument. The district court acknowledged that

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13. At oral argument, the appellants emphasized that Mylan was delayed for two-and-a-half years in filing its ANDA and challenging the patents because it believed that Barr was entitled to the 180-day exclusivity period. Oral Arg. at 5:56-6:29, 6:49-7:02, *available at* http://www.cafc.uscourts.gov/oralarguments/mp3/2008-1097.mp3. They further asserted that because of the delay, none of the generic challengers raised the issue of inequitable conduct. *Id.* at 7:05-7:57.

two circuit courts issued opinions in April 1998, more than a year after the Agreements were executed, striking down the FDA regulation. *Cipro I*, 261 F.Supp.2d at 243-44 (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C.Cir.1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir.1998)). The court further noted that the FDA ultimately removed the successful defense requirement from the regulation in November 1998. *Cipro I*, 261 F.Supp.2d at 244 (citing 63 Fed.Reg. 59710, 59711 (Nov. 5, 1998)). Nevertheless, the court correctly concluded that "the fact still remains that the requirement was in effect at the time of the [Agreements]." *Cipro I*, 261 F.Supp.2d at 244; *see Tamoxifen*, 466 F.3d at 218 (concluding that because the established law at the time of the settlement agreement required that a generic manufacturer must successfully defend an infringement lawsuit in order to obtain exclusivity, the generic manufacturer had no claim to the exclusivity period despite the terms of the agreement). Furthermore, the court appreciated that even without the successful defense requirement, there was still no support for the claim that Barr retained the 180-day exclusivity period after amending from a Paragraph IV ANDA to a Paragraph III ANDA.[14] *Cipro*

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14. Although the Agreements apparently did contain a provision preserving the option for Barr to reamend to a Paragraph IV ANDA (presumptively for the purpose of reclaiming the 180-day exclusivity period) if the '444 patent was subsequently declared by a court to be invalid or unenforceable, that provision does not change the analysis. Under the FDA regulations in effect at the time of the

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I, 261 F.Supp.2d at 247. Finally, the court recognized that since the Agreements were executed, Bayer has sued four other generic manufacturers that filed ANDAs and defended against invalidity counterclaims; thus, the Agreements did not prevent other generic manufacturers from challenging the '444 patent. *Id.* We find no error by the district court in declining to consider anew the evidence allegedly showing that the Agreements preserved Barr's claim to the 180-day exclusivity period, and in concluding that the Agreements did not create a "bottleneck" for other generic manufacturers.

Accordingly, we affirm the district court's grant of summary judgment on Counts I-IV, holding that the Agreements were not violative of section 1 of the Sherman Act since all anticompetitive effects were within the exclusionary power of the '444 patent.

IV

Count V alleges that Bayer violated state antitrust and consumer protection laws by fraudulently obtaining the '444 patent and enforcing it through sham litigation. The district court dismissed Count V as preempted by federal patent law. *Cipro II*, 363 F.Supp.2d at 547.

(Cont'd)

Agreements, the first generic manufacturer was not entitled to the 180-day exclusivity period unless it had satisfied the successful defense requirement. Furthermore, since the option was never exercised, there was no evidence of an *actual* adverse effect on competition due to that provision. *See Clorox*, 117 F.3d at 56.

Appendix A

The appellants challenge the district court's dismissal of Count V, arguing under *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed.Cir.1998), and *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed.Cir.1998), that the court erred in concluding that their state law monopolization claims are preempted by federal patent law because preemption does not apply when the patent was procured by fraud. Further, the appellants contend that the district court erroneously concluded that no tortious conduct in the marketplace had been alleged, ignoring Bayer's lawsuit against Barr seeking to enforce a fraudulently procured patent. According to the appellants, the district court's reliance on *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368 (Fed.Cir.2000), and *Abbott Laboratories v. Brennan*, 952 F.2d 1346 (Fed.Cir.1991), is misplaced because neither case involves a state law antitrust claim based on wrongful enforcement of a patent procured by fraud. The appellants assert that an antitrust claim under *Walker Process* is distinguishable from an inequitable conduct claim because it contains the additional elements of an antitrust claim, namely, market power and antitrust injury. The monopolization claims here, the appellants contend, like those in *Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470 (Fed.Cir.1998), have elements other than inequitable conduct before the PTO—and therefore are not preempted by federal patent law. Finally, the appellants argue that because antitrust is a field traditionally regulated by the states, there is a presumption against preemption of state law, and

Congress has made no express legislative statement to overcome that presumption.

It is not clear that the district court considered the portions of *Hunter Douglas* and *Nobelpharma* that the appellants rely on in their brief. However, the result in this case would not change even if we were to adopt the appellants' interpretation of these cases because the district court determined, and we agree, that no fraud occurred. In light of this, the district court's disposition of Count V was not erroneous.

V

For the foregoing reasons, we affirm the grant of summary judgment by the District Court for the Eastern District of New York that the Agreements were not in violation of section 1 of the Sherman Act because any anti-competitive effects caused by the Agreements were within the exclusionary zone of the patent. We further affirm the court's dismissal of the state antitrust claims.

AFFIRMED

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT FILED NOVEMBER 7, 2007

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of November, two thousand seven,

Present:

Hon. Roger J. Miner,
Hon. Rosemary S. Pooler,
Circuit Judges.[1]

05-2851-cv (L)
05-2852-cv (CON)
05-2863-cv (CON)

In re Ciprofloxacin Hydrochloride Antitrust Litigation.

Defendants-Appellees move to transfer to the United States Court of Appeals for the Federal Circuit these

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1. The Honorable Thomas J. Meskill, who was originally assigned to the panel, died before oral argument. The remaining two members of the panel, who are in agreement, decide this case in accordance with Second Circuit Local Rule 0.14(b).

three appeals. Upon due consideration, it is hereby ORDERED that the motion is GRANTED as to the appeal docketed under 05-2863-cv, which is TRANSFERRED to the Federal Circuit because the *Walker Process* claim in that case arises out of patent law. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988) (finding that a case "arises under" federal patent law if "a well-pleaded complaint establishes ... that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims").

However, the motion is DENIED as to the appeals docketed under 05-2851-cv and 05-2852-cv because the claims therein rely on several theories, including alternative theories that do not require the determination of any substantial question of patent law. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2006) (finding that "even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction under 28 U.S.C. § 1338"); *see also Christianson*, 486 U.S. at 809 (finding that a case raising a patent law defense will not, for that reason alone, be said to "arise under" patent law, "even if the defense is anticipated in the complaint").

Thus, the appeal docketed under 05-2863-cv is transferred to the Federal Circuit, while the appeals

docketed under 05-2851-cv and 05-2852-cv will remain consolidated in this Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

By: s/ Lucille Carr

APPENDIX C — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK DECIDED MARCH 31, 2005

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

1:00-MDL-1383 (DGT)

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

March 31, 2005, Decided

JUDGES: David G. Trager, United States District Judge.

OPINION BY: David G. Trager

OPINION

MEMORANDUM AND ORDER

TRAGER, District Judge.

This action involves agreements between the brand-name manufacturer of the widely used antibiotic ciprofloxacin hydrochloride ("Cipro") and potential generic manufacturers of Cipro. The brand-name manufacturer, Bayer AG, a German company, and its American subsidiary, Bayer Corporation (collectively, "Bayer") and the generics, Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst

Appendix C

Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "generic defendants")[1] entered into agreements that Direct Purchaser Plaintiffs ("direct plaintiffs") and Indirect Purchaser Class Plaintiffs ("indirect plaintiffs") allege prevented competition in the market for Cipro in violation of federal and state antitrust laws.[2] Plaintiffs previously filed motions for partial summary judgment seeking a determination that these agreements were *per se* unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (and various state antitrust and consumer protection laws), which were denied. Subsequently, indirect plaintiffs amended their complaint to add a new count, Count V, alleging *Walker Process*-type[3] and sham litigation antitrust violations under state law.

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1. Barr and Rugby are in the business of, *inter alia*, manufacturing and marketing generic drugs. Rugby was the U.S. generic drug subsidiary of HMR until February 1998, when Rugby was acquired by Watson, a company that produces and distributes generic and brand-name drugs. Watson is not a signatory to any of the allegedly unlawful agreements.

2. The generic defendants, together with Bayer, will be referred to as the "defendants," while direct plaintiffs and indirect plaintiffs will be referred to as "plaintiffs."

3. In *Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court first recognized an antitrust cause of action based on assertion of a patent known to have been obtained by fraud on the United States Patent and Trademark Office ("PTO"), provided that the other elements of a Sherman Act claim are present. Such claims are commonly referred to as

(Cont'd)

Appendix C

Bayer and generic defendants have now each filed motions for summary judgment asserting that these agreements do not violate Section 1 of the Sherman Act because they had no anti-competitive effects beyond the scope of Bayer's patent on ciprofloxacin, while direct plaintiffs have filed a motion for partial summary judgment arguing that the agreements meet the "anti-competitive conduct" requirement of Section 1 of the Sherman Act and the "antitrust injury" requirement of the Section 4 of the Clayton Act. Bayer has also filed two motions relating to Count V of indirect plaintiffs' second amended complaint ("Count V"). The first, a motion to dismiss Count V, is made on the grounds that indirect plaintiffs' state law *Walker Process*-type claim is preempted by federal patent law and is barred by the statute of limitations. The second, filed in the event Count V is not dismissed, is a motion for summary judgment on Count V on the grounds that indirect plaintiffs have failed to demonstrate that any misrepresentations or omissions made by Bayer in prosecuting its patent were so highly material that the patent would not have issued but for the alleged deceptions and that plaintiffs' sham litigation claim fails as a matter of law. Finally, HMR and Rugby have filed a motion for summary judgment that indirect plaintiffs' claims against them are barred by the doctrine of

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(Cont'd)

Walker Process claims. Because indirect plaintiffs are asserting their claims under state law and because they have pointed to no state law explicitly recognizing an antitrust claim for assertion of a patent obtained by fraud, their claim is referred to as a *Walker Process*-type claim.

Illinois Brick[4] and that any rights assigned to indirect plaintiffs do not include claims against HMR.

Background

The statutory and regulatory background, as well as the circumstances of this case, were fully described in the court's initial opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F.Supp.2d 740 (E.D.N.Y.2001) ("*Cipro I*") (granting certain plaintiffs' motions to remand to state court). The developments in the case were further discussed and analyzed in a second opinion, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188 (E.D.N.Y.2003) ("*Cipro II*") (granting in part and denying in part defendants' motions to dismiss, and denying plaintiffs' motion for partial summary judgment asserting that the agreements constituted *per se* violations of the antitrust laws). Familiarity with those decisions is presumed, and what follows is a summary of only those facts necessary for the resolution of the pending motions.

Bayer is the assignee of U.S. Patent No. 4,670,444 ("the '444 Patent"), a compound patent which claims the chemical entity that is the active ingredient in Cipro-ciprofloxacin hydrochloride-and all its generic equivalents. *See Cipro II*, 261 F.Supp.2d at 249 ("A

4. Under *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), indirect purchasers are barred from recovering damages for monopolistic overcharges under federal antitrust law.

patent on a compound that is the only active ingredient in a drug covers all generic versions of that drug . . . . regardless of how formulated, processed or delivered . . . . "). The '444 Patent issued on June 2, 1987 from patent application Ser. No. 614,923 ("the '923 application"), which was filed on May 29, 1984. The '923 application was filed as a continuation-in-part[5] of Ser. No. 292,560 ("the '560 application"), which was filed on August 13, 1981, and Ser. No. 436,112 ("the '112 application"), which was filed on October 22, 1982. *See* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V App."), Ex. 1.

In October 1987, Bayer's predecessor, Miles, Inc., obtained FDA approval to market Cipro in the United States. *Cipro II*, 261 F.Supp.2d at 194. From 1987 until 2004, Bayer was the only producer of Cipro in the United States. *Id.* On October 22, 1991, Barr filed Abbreviated New Drug Application ("ANDA") 74-124 for permission to market a generic version of Cipro, and included a Paragraph IV certification, seeking permission to market its generic drug before expiration of the '444 Patent on the grounds that the patent was invalid and unenforceable. *Id.* Because the '444 Patent claims the active ingredient in Cipro and because Barr was required in its ANDA to certify that its generic version

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5. A continuation-in-part application is an application that claims priority to and includes the subject matter of at least part of an earlier-filed application.

of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent. *Cipro II*, at 249; *see also* App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Pls. Claims Under the Sherman Act and Corr. State Law Claims ("Bayer Sherman Act App."), Tab 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)).

Pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, on December 6, 1991, Barr notified Bayer of its ANDA IV filing, and on January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York, where the case was assigned to Judge Whitman Knapp. *Cipro II*, 261 F.Supp.2d at 194. In January 1996, Bayer and Barr filed cross-motions for partial summary judgment, which Judge Knapp denied in an order and opinion dated June 5, 1996. *Id.* at 195. In March 1996, while these cross-motions were *sub judice*, Barr agreed to share equally any profits from the eventual marketing and/or distribution of Cipro with Rugby, which was then a subsidiary of HMR, and, in return, Rugby agreed to finance a portion of the costs and expenses of the patent litigation against Bayer. *Id.*

On January 8, 1997, just weeks before trial was scheduled to begin, Bayer and Barr reached a settlement of the patent litigation, with Bayer entering into three separate agreements with Barr, HMR and Rugby, and Bernard Sherman and Apotex, Inc. (collectively, the "Settlement Agreements") and a supply

agreement with Barr and HMR (the "Supply Agreement") (collectively with the Settlement Agreements, the "Agreements"), the terms of which give rise to the plaintiffs' claims of Sherman Act violations. *Id.* at 195-96. Under the Barr Settlement Agreement, Bayer paid Barr $49.1 million and, in return, required Barr to amend its ANDA from a Paragraph IV certification to a Paragraph III certification, which would permit it to market a generic form of Cipro only upon the expiration of the '444 Patent. *Id.* at 196. However, the Barr Settlement Agreement preserved the option for Barr to re-amend to a Paragraph IV certification (for the purpose of reclaiming the 180-day exclusivity period that is awarded to a first-filer of an ANDA IV) in the event the '444 Patent were subsequently declared invalid or unenforceable by a court of competent jurisdiction. Bayer Sherman Act App., Ex. 16 ¶ 5(a); *see Cipro II*, 261 F.Supp.2d at 243-47.

Under the terms of the Supply Agreement, Barr and HMR agreed not to manufacture or have manufactured a generic form of Cipro in the United States. *Cipro II*, 261 F.Supp.2d at 196. The Supply Agreement further provides that Bayer will either supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, or make quarterly payments to Barr from January 1998 through December 2003, at which time the '444 Patent was due to expire. *Id.* Bayer opted to make the payments, which, by December 2003, when added to the initial $49.1 million payment, totaled approximately $398 million. *Id.*

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Bayer and Barr also entered into a Consent Judgment, terminating the litigation, in which Barr affirmed the validity and enforceability of the '444 Patent and admitted infringement. *Id.* at 196; Bayer Sherman Act App., Ex. 18. The Consent Judgment was signed by Judge Knapp, but made no mention of any payments from Bayer to Barr. *Id.*

Six months after settling with Barr, in July 1997, Bayer submitted the '444 Patent to the Patent and Trademark Office ("PTO") for reexamination. During the reexamination, Bayer amended certain of the claims of the '444 Patent and cancelled others, after which the PTO reaffirmed the patent's validity, including the validity of claim 12, which was not substantively amended and which all parties agree covers ciprofloxacin hydrochloride. *Id.* at 197; Bayer's Reply Mem. in Supp. of Its Mot. for Partial Summ. J. on Count V of the Indirect Purchaser Class Pls.' Proposed Second Am. Consolidated Class Action Compl. ("Bayer's Count V Reply Mem.") at 19; Bayer Sherman Act App., Ex. 5; App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V S.J.App."), Ex. 9. Thereafter, four other generic companies-Schein, Mylan, Carlsbad and Ranbaxy-each challenged the reexamined '444 Patent by filing ANDA IVs for Cipro. *Cipro II*, 261 F.Supp.2d at 197. Bayer defeated Schein and Mylan's validity challenges on summary judgment, and those decisions were upheld by the Court of Appeals for the Federal Circuit. *Id.* at 201. The Carlsbad case proceeded to a

nine-day bench trial, after which the judge rejected Carlsbad's invalidity argument and upheld the validity of the '444 Patent. *See* Bayer Count v.App., Exs. 15 and 16 (*Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 5-13 (S.D. Cal. June 7, 2002 and Aug. 7, 2002)). Ranbaxy's challenge was dismissed as moot after Ranbaxy withdrew its Paragraph IV certification. *Cipro II*, 261 F.Supp.2d at 197.

Discussion

(1)

Sherman Act Motions for Summary Judgment

The *Cipro II* decision made clear that Barr's agreement with Bayer not to sell ciprofloxacin in exchange for the exclusion payments, also commonly known as reverse or exit payments,[6] did not constitute a *per se* violation of the Sherman Act because the exclusionary effect of the Agreements was within the scope of the '444 Patent. Direct plaintiffs now move for summary judgment that the exclusion-payment scheme meets the "anti-competitive conduct" requirement of Section 1 of the Sherman Act under a rule of reason analysis, while both Bayer and generic defendants move

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6. In briefing these motions, the parties have sometimes referred to these payments as "reverse" payments. Adoption herein of the "exclusion payments" nomenclature is made for ease of reference, and in recognition that the payments, whatever they are called, are made in exchange for a competitor's exit or exclusion from the relevant market.

for summary judgment that the Agreements had no anti-competitive effects that are actionable under the Sherman Act because they were within the scope of the '444 Patent. Resolution of this issue requires a close look at the intersection of patent and antitrust laws.

The rule of reason analysis involves a three-step process. First, the plaintiff must prove that "the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market." *K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir.1995) (emphasis in original) (quoting *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.), *cert. denied*, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993)). Next, "the burden shifts to the defendant to establish the 'pro-competitive redeeming virtues' of the action." *Id.* If the defendant succeeds, the burden shifts back to the plaintiff to "show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." *Id.*[7,8]

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7. Summary judgment is appropriate only in those cases where there is no genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Here, Bayer, generic defendants and direct plaintiffs have each filed motions for summary judgment on the issue of whether the Bayer/Barr settlement agreements had an anti-competitive effect. The burden of proving anti-competitive effects lies with the plaintiffs in the first instance, and, as discussed *infra*, plaintiffs have shown no anti-competitive effects beyond the scope of the '444 Patent. The analysis with

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Appendix C

a. Relevant market

Taking these steps one at a time, the first question is whether plaintiffs have shown that the Agreements had an actual adverse effect on competition in the relevant market. Traditionally, the starting point of an antitrust inquiry is the definition of the relevant market. *See, e.g., Geneva Pharma. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir.2004) ("Evaluating market power begins with defining the relevant market."). The purpose of this inquiry is to determine whether

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respect to those anti-competitive effects that are within the scope of the '444 Patent (and which all parties agree were present) constitutes a pure discussion of law without regard to burdens of proof.

8. A recent decision by the Eleventh Circuit questions the appropriateness of the *per se* versus rule of reason approach for claims of antitrust violations involving patents. *See Schering-Plough v. Federal Trade Comm'n*, 402 F.3d 1056, 1065-1066, 2005 WL 528439, at *7 (11th Cir. Mar.8, 2005). The Eleventh Circuit's opinion can fairly be read as breaking the first step of a rule of reason analysis-assessing the actual adverse effects on competition-into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent. Regardless of whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis, the case at bar will be considered under this court's prior opinion adopting the rule of reason mode of analysis. *See Cipro II*, 261 F.Supp.2d at 256-57. It would be inappropriate not to address the issue accordingly, not least because the parties have briefed the issue in light of that analysis. In any event, the same result would be reached under either analytical approach.

defendants possess market power, *i.e.*, the ability to lessen or destroy competition, which, while not the *sine qua non* of a violation of Section 1 of the Sherman Act, is "a highly relevant factor in rule of reason analysis because market power bears a particularly strong relationship to a party's ability to injure competition." *Capital Imaging*, 996 F.2d at 546. The parties dispute whether the relevant market comprises only ciprofloxacin, as plaintiffs have asserted in their complaint, *see* Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 34, or includes other drugs in the same molecular family as ciprofloxacin (flouroquinolones), which Bayer contends compete with ciprofloxacin in the U.S. antibiotic market, *see* Bayer Defs.' Mem. of Law in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Bayer's Opp. Mem."), at 26-29.

Plaintiffs assert that it is unnecessary to show a relevant market in this case because there exists direct evidence of anti-competitive effects. Mem. in Support of Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Dir. Pls.' Mem."), at 25. In general, to sidestep the traditional relevant market analysis, a plaintiff must show by direct evidence "an actual adverse effect on competition, such as reduced output." *Geneva v. Barr*, 386 F.3d at 509 ("If plaintiff can demonstrate an actual adverse effect on competition, such as reduced output, . . . there is no need to show market power in addition.") (citing *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986); *K.M.B. Warehouse*, 61 F.3d at 128-29). The reason for permitting this alternative showing is simply that the purpose of

an inquiry into market power "is to determine whether an arrangement has the potential for genuine adverse effects on competition." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 460, 106 S.Ct. at 2019, 90 L.Ed.2d 445. In effect, market power is "but a 'surrogate for detrimental effects.' " *Id.*, 476 U.S. at 461, 106 S.Ct. at 2019 (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

For their direct evidence showing, direct plaintiffs point to government and academic studies concluding that purchasers derive substantial savings from the availability of generic drugs; internal analyses by the brand name and generic manufacturers themselves forecasting significant price reductions once generic drugs become available; and sales data showing the actual effects of competition once generic Cipro was introduced into the market. Dir. Pls.' Mem. at 25-31. In particular, direct plaintiffs rely on a 1998 study by the Congressional Budget Office comparing brand-name and generic prices for twenty-one different drugs that faced generic competition between 1991 and 1993, which *522 found that the average retail price of a prescription for a generic drug in 1994 was less than half the average brand-name drug price. App. in Support of Decl. of Monica L. Rebuck for Dir. Pls.' Mot. for Partial Summ. J. (Dir. Pls.' Summ. J.App.), Tab 5 (Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 28-31 (July 1998) ("CBO Study")). Another study cited by direct plaintiffs found that by 2000, the average brand-name prescription cost

340 percent more than its generic equivalent ($65.29 versus $19.33). Dir. Pls.' Summ. J.App., Tab 20 (Kirkling et al., *Economics and Structure of the Generic Pharmaceutical Industry,* 41 J. Amer. Pharm. Assoc. 578, 579 (2001)).

These studies notwithstanding, the significant price differences actually suggest a finding contrary to the one implied by plaintiffs. Namely, brand-name pharmaceuticals and their generic counterparts might not always compete in the same markets at all because, based on the higher prices of the brand-name drugs, there is less cross-elasticity of demand than one might expect. (If there were, the prices for brand-name drug prices should fall and be closer to that of generics). Indeed, the CBO Study cited by plaintiffs indicates that prices for brand-name drugs continue to rise faster than inflation even after generic competition begins. CBO Study at 30-31. The Second Circuit recently relied on similar price differential data to reach a particularly narrow market definition in *Geneva v. Barr,* 386 F.3d at 496-500. In that case, the court, relying on the factors set forth in *Brown Shoe Co. v. United States,* 370 U.S. 294, 325, 82 S.Ct. 1502, 1524, 8 L.Ed. 1264 (1962), defined the market as limited to *generic* warfarin sodium. *Id.; see also Asahi Glass Co., Ltd. v. Pentech Pharma., Inc.,* 289 F.Supp.2d 986, 995-96 (N.D.Ill.2003) (Posner, J., sitting by designation) (noting that paroxetine, the active ingredient in Paxil, competes with molecules that are the basis for other antidepressant drugs such as Prozac and Zoloft, but reserving the possibility that paroxetine might still warrant treatment as a separate market).

Appendix C

Despite the fact that brand-name pharmaceuticals are apparently able to maintain significantly higher prices even after generic entry, the parties' internal analyses prepared at the time the Agreements were entered into confirm that both Bayer and Barr expected Bayer to lose significant sales once generic competition began, with Bayer estimating losses of between $510 million and $826 million in Cipro sales during the first two years of generic competition, depending on the number of generic manufacturers entering the market. Dir. Pls.' Summ. J.App., Tab 47A, at BCP4630078. Another contemporaneous internal Bayer document estimated Bayer's losses due to a potential adverse judgment in the '444 Patent litigation at $1.679 billion net present value. Dir. Pls.' Summ. J.App., Tab 47D at BCP-P-0001572-004(2). Barr, similarly, projected that it and other generic manufacturers would capture a large percentage of the market for ciprofloxacin within the first two years of generic competition, and would enter the market at a 30 percent discount off Bayer's price. Dir. Pls.' Summ. J.App., Tab 36A at BLI-003560.

Finally, direct plaintiffs point to post-generic entry data showing that Barr in fact did capture more than 50 percent of Bayer's Cipro sales soon after entering the market, and that it initially priced its generic ciprofloxacin at only 8 percent below Bayer's Cipro product. Dir. Pls.' Summ. J.App., Tab 35 (Expert Report of Jeffrey J. Leitzinger, Ph.D., at 38 n. 93). Direct plaintiffs also note that the Amended and Restated Supply Agreement between Bayer and Barr, dated August 28, 2003, which provides for Bayer to continue

supplying ciprofloxacin to Barr for resale after expiration of the pediatric marketing exclusivity extension that Bayer obtained pursuant to 21 U.S.C. § 355a, sets drastically reduced prices for Cipro after the commencement of open generic competition. Dir. Pls.' Summ. J.App., Tab 43A at BCP4660023. For example, a 100-pill bottle of oral, 500-mg ciprofloxacin that cost Barr $321.96 before the beginning of open generic competition would cost only $14.30 after the expiration of Bayer's pediatric exclusivity, a 95 percent difference in price. *Id.* Bayer has admitted that the purpose of the price drop was to allow Barr to compete with additional generic manufacturers who would then be entering the market. Dir. Pls.' Summ. J.App., Tab 80 at 112.

Bayer discounts the import of these facts, insisting instead that Cipro competes in the larger market of flouroquinolones, which includes other drugs such as Levaquin, Floxin and Noroxin, within which Cipro has been losing market share, from 75 percent in 1996 to 43 percent in 2001. Bayer's Opp. Mem. at 28-29. Bayer maintains that a properly defined market must include all quinolone antibiotics and that defendants did not possess enough market power to control prices or exclude competition within that larger market. *Id.* at 29.

Although evidence that Bayer charged high prices for Cipro "may of course be indicative of monopoly power," it is not necessarily conclusive in the absence of any analysis of Bayer's costs. *See, e.g., Geneva Pharm.*

v. Barr, 386 F.3d at 500. Plaintiffs have provided neither evidence of Bayer's costs nor any direct evidence that defendants restricted output. However, the pricing strategy encompassed in the Amended and Restated Supply Agreement compels an inference that Bayer was reaping an abnormally high price-cost margin, given the 95 percent price drop that was to occur almost a full year in the future for an identical quantity of an identical strength of the identical drug. Dir. Pls.' Summ. J.App., Tab 43A at BCP4660023. Given Bayer's obvious ability to control prices, and its admission that it did not anticipate a commensurate drop in its own production costs for Cipro,[9] it is reasonable to accept plaintiffs' contention and conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market.

b. Adverse effect on competition

The ultimate question-and this is the crux of the matter-is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition

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9. Bayer admitted at oral argument that its estimated costs of production did not change after the exclusivity period, but contends that its marketing costs were projected to drop sharply after generic entry. It is understandable that Bayer would choose to spend less to promote Cipro at a time when its marketing efforts would not redound exclusively to its own benefit, but a drop in such discretionary spending only further illustrates the degree to which Bayer controlled its own profit margin.

stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. *See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816, 65 S.Ct. 993, 998, 89 L.Ed. 1381 (1945) (A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market."); *Schering-Plough*, 402 F.3d 1056, 1065-1066, 2005 WL 528439, at *7 ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present."). However, any adverse effects within the scope of a patent cannot be redressed by antitrust law. *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C.Cir.1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent and is otherwise legal."); *see also United States v. General Electric Co.*, 272 U.S. 476, 485, 47 S.Ct. 192, 195, 71 L.Ed. 362 (1926); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91, 22 S.Ct. 747, 755, 46 L.Ed. 1058 (1902). The '444 Patent gave Bayer the right to exclude competition entirely for ciprofloxacin for the term of the patent, and any conduct within the scope of the patent is exempt from antitrust scrutiny. *See Cipro II*, 261 F.Supp.2d at 248 ("[A] patent holder does not run afoul of the Sherman Act unless the patent holder acts beyond the confines of the patent monopoly."). Defendants argue that a determination that the Agreements do not restrict competition beyond the scope of the claims of the '444 Patent ends the inquiry as to anti-competitive effects.

Plaintiffs, on the other hand, argue that the exclusionary power of the patent for purposes of the anti-competitive effects analysis should be tempered by its potential invalidity.

i. The validity inquiry

While there have been to date only a handful of cases discussing the legality of patent settlement exclusion payments, some courts and commentators have dealt with the questions of whether and to what extent the validity of the patent should be a factor in appraising the legality of an exclusion payment, and what sort of inquiry into validity an antitrust court should make. The Second Circuit has not yet addressed these issues, but two federal circuits, two district courts (including one on which Judge Posner sat by designation) and the Federal Trade Commission ("FTC") have considered them. Although those courts have come to different conclusions regarding the legality of exclusion payments at issue in those cases, they have generally agreed that an antitrust court need not make an independent assessment of the underlying patent's validity.

The Eleventh Circuit's approach in *Valley Drug*

The Eleventh Circuit in *Valley Drug Co. v. Geneva Pharma., Inc.*, 344 F.3d 1294 (11th Cir.2003), held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* (or rule of reason) antitrust condemnation, even

where the patent is later held invalid. *Valley Drug*, 344 F.3d at 1311. The two agreements at issue in that case were between Abbott, manufacturer of the pioneer drug Hytrin, and two of its generic competitors-Geneva and Zenith. *Id.* at 1296. Abbott held multiple patents on Hytrin, a drug containing terazosin hydrochloride, which is used to treat hypertension and enlarged prostate, and Geneva filed several ANDA IVs on Hytrin over a period of years. *Id.* at 1298. Zenith, meanwhile, had also filed an ANDA IV on Hytrin, which was pending when two additional patents relating to the active ingredient in Hytrin were issued to Abbott. *Id.* Abbott listed the new patent information with the FDA, which then required Zenith to make a certification with respect to the newly-issued patents. *Id.* Rather than comply, Zenith filed suit against Abbott to force Abbott to delist the new patents, alleging that Abbott listed them with the knowledge that they were not applicable to Hytrin. *Id.*

On March 31, 1998, Abbott and Zenith entered an agreement settling their delisting and infringement dispute, under which Zenith agreed not to sell or distribute any generic terazosin hydrochloride product until a third party entered the market or until one of Abbott's patents expired, in exchange for payments by Abbott of $6 million every three months. *Id.* at 1300. The next day, Abbott entered a similar agreement with Geneva whereby Geneva agreed not to sell or distribute any generic terazosin hydrochloride product until one of Abbott's patents expired, a third party entered the market or Geneva obtained a final court judgment from which no further appeal could be taken that its terazosin

products did not infringe one of Abbott's patents or that the patent was invalid. *Id.* In exchange, Abbott agreed to pay Geneva $4.5 million per month. *Id.* Geneva subsequently prevailed in the patent infringement suit Abbott had filed against it, obtaining a judgment on September 1, 1998 that the patent at issue in that case was invalid. *Id.* at 1301.

The district court concluded that Abbott's agreements with Zenith and Geneva were *per se* violations of Section 1 of the Sherman Act, holding that the exclusionary effect of the agreements constituted an allocation of the market between horizontal competitors. *Id.* at 1304. The Eleventh Circuit reversed, however, rejecting the argument "that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid." *Id.* at 1306. The court ruled that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Id.* at 1306-07. The court invoked the rationale of Justice Harlan's concurrence in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80, 86 S.Ct. 347, 351-52, 15 L.Ed.2d 247 (1965): "[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or

punitive consequences of treble-damage suits." *Id.* at 1307. The court accordingly reserved any *post hoc* validity analysis for those cases in which the patent was procured by fraud or known by the patentee to be invalid. *Id.* at 1307.

The court concluded that "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent." *Id.* at 1308. The court held open the possibility that the size of the payment to refrain from competing could be evidence of a lack of faith in the validity of the patent or evidence that the patent was obtained by fraud but, citing this court's decision in *Cipro II*, noted that the asymmetries of risk inherent in a Hatch-Waxman patent litigation and the high profits at stake could induce even a confident patentee to pay a substantial sum in settlement. *Id.* at 1309-10.

The *Valley Drug* court thus took the position that an antitrust court need not consider the potential invalidity of the patent in an exclusion-payment settlement, except in those extreme cases involving fraud on the Patent Office or assertion of a patent known to be invalid, *i.e.*, in circumstances giving rise to an allegation of *Walker Process* fraud or sham litigation. However, the court went on to direct the district court on remand to evaluate the *526 defendants' claim that the exclusionary effects of the patent and the

agreements were coextensive because certain provisions of the agreements were analogous to a consensual preliminary injunction and stay of judgment pending appeal. *Id.* at 1312. The court instructed that this evaluation should include a comparison between "the provisions of the agreement and the protections afforded by the preliminary injunction and stay mechanisms," and, furthermore, that the "likelihood of Abbott's obtaining such protections" should be considered. *Id.*

On remand, the district court interpreted the Eleventh Circuit's instructions as requiring an analysis of the likelihood that Abbott would have won a preliminary injunction at the time the agreements were executed, which it construed as requiring an analysis of whether Abbott would have been able to show that its patent was likely valid, rather than an analysis simply of whether the patent claims covered Abbott's product. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F.Supp.2d 1279, 1295 (S.D.Fl.2005). The district court proceeded to determine the likely validity of the patent at the time the agreements were entered, employing the standards applicable to a preliminary injunction analysis. *Id.* at 1303-07. The district court ultimately concluded that Abbott would likely not have been able to show that its patent was likely valid at the preliminary injunction stage of its suit against Geneva and, therefore, held that the Geneva agreement went beyond the exclusionary zone of the patent and was a *per se* violation of the Sherman Act.

It is not certain that the district court correctly interpreted the Eleventh Circuit's opinion, and, indeed, the Eleventh Circuit seems to have expressed some doubt on that point in an unrelated opinion. *See Schering-Plough*, 402 F.3d at 1065, 2005 WL 528439, at *7 n. 14 ("On remand, the district court in *Valley Drug* still applied a *per se* analysis. . . ."). In any event, the implication of the district court's reasoning conflicts with the proposition already rejected in *Cipro II*-that the legality of the Agreements is contingent on Barr's chances of having won at trial. *See Cipro II*, 261 F.Supp.2d at 202 ("[P]laintiffs cannot avoid dismissal based on a claim of injury-in-fact that relies on the hope that Barr would have prevailed in its suit against Bayer.").

The Sixth Circuit's approach in *Cardizem*

The Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir.2003), also eschewed an analysis of the patent's validity in analyzing the anti-competitive effects of an exclusion-payment patent settlement agreement, although that court, unlike this one, concluded that such a settlement was a *per se* violation of the Sherman Act without considering the scope of the underlying patent right. The agreement at issue in that case, however, contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law, particularly because the settling generic manufacturer, Andrx, did not relinquish its claim to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. That is, a term

of the agreement required that Andrx maintain its status as first-filer of an ANDA IV even after entering the agreement with the brand-name manufacturer. *In re Cardizem*, 332 F.3d at 902. Andrx's refusal to amend its ANDA to give up the exclusivity claim resulted in a market bottleneck since no other generic manufacturer could come to market until at least 180 days after Andrx began marketing the drug, a trigger that was postponed indefinitely by the settlement. *Id.* at 907. Thus, the brand-name manufacturer used the agreement to effectively bar third parties from mounting challenges to its patent-a power clearly not within the exclusionary power of a patent. Therefore, although the Sixth Circuit arrived at a different conclusion regarding *per se* liability, its approach was consistent with the position taken by this court in *Cipro II*-namely, that a patent holder cannot exploit the Hatch-Waxman provisions to create a bottleneck that indefinitely excludes subsequent generic challengers from the market. It is also clear that the Sixth Circuit did not engage in an after-the-fact analysis of the patent's likely validity in reaching its determination.

Judge Posner's approach in *Asahi Glass*

Judge Posner, sitting by designation for the Northern District of Illinois, adopted similar reasoning to that of the Eleventh Circuit in *Valley Drug* in analyzing the merits of an antitrust action brought by a supplier to a generic pharmaceutical company that was shut out of the market for paroxetine hydrochloride (sold as the antidepressent Paxil) by a settlement

agreement between the generic and the brand-name manufacturer. *Asahi Glass*, 289 F.Supp.2d at 992-93. The agreement settled a Hatch-Waxman patent litigation and stipulated that the brand-name manufacturer would provide the finished drug product free of charge to the generic company, which would then sell it as an unbranded version of Paxil and pay a sizeable royalty to the brand-name manufacturer. The plaintiff, which had previously anticipated selling the active ingredient for the drug to the generic manufacturer, found itself without a customer, since the generic manufacturer had no incentive to pay for that which it was already getting for free from the brand-name drug maker. The plaintiff sued both parties to the agreement, alleging that the agreement violated Section 1 of the Sherman Act. Judge Posner dismissed the complaint on the ground that the agreement was a legitimate settlement of a patent infringement suit. *Id.* at 991.

Commenting on the hesitation of an antitrust court to delve into the merits of a predicate patent suit and its potential effect on a settlement agreement, Judge Posner noted:

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent,

> 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Id. at 992-93. Although *Asahi Glass* did not involve an exclusion-payment settlement, Judge Posner employed a similar approach to that of the Eleventh Circuit in *Valley Drug* in declining to independently assess the likely validity of the patent unless it was almost certainly invalid or obtained by fraud.[10, 11]

The district court's approach in *Tamoxifen*

This district has also previously adjudicated the legality of a settlement of a patent litigation in which the validity of the patent was less than certain, without engaging in a *post hoc* analysis of the patent's validity. *See In re Tamoxifen Citrate Antitrust Litig.*, 277

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10. Neither the Eleventh Circuit nor Judge Posner furnished any examples of or provide further guidance regarding patents that were so blatantly invalid.

11. It happens that Judge Posner did in fact decide the validity of the patent in a related patent infringement case that was decided prior to *Asahi Glass*. *See Asahi Glass*, 289 F.Supp.2d at 992. In that case he found the patent to be valid. *Id.*

F.Supp.2d 121 (E.D.N.Y.2003) (Glasser, J.). In that case, the brand-name manufacturer, Zeneca, settled with the first generic challenger-coincidentally, Barr-after Barr had obtained a district court judgment, at that time on appeal, that the patent was invalid and unenforceable. *Id.* at 125. Under the settlement, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca for a royalty in exchange for Barr's withdrawal of its challenge to the validity to the patent and agreement not to market its generic version of tamoxifen until the patent expired. *Id.* Barr and Zeneca jointly moved the appeals court to dismiss the appeal as moot in light of the settlement and to vacate the judgment below, which motions were granted. *Id.* Three additional generic manufacturers subsequently challenged Zeneca's patent for tamoxifen, and the patent was upheld in each instance, despite an attempt by one of the challengers to invoke collateral estoppel based on Barr's earlier vacated district court judgment. *Id.* at 126-27.

The district court dismissed the subsequent antitrust action brought by consumers, third-party payors and consumer advocacy groups alleging that they were forced to pay higher prices for tamoxifen as a result of the Zeneca/Barr settlement agreement. The court reasoned: "The lack of competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it." *Id.* at 138. In reaching this conclusion, the court did not independently assess the probable validity of the patent,

even in light of the earlier district court's finding of invalidity and unenforceability, although it did note the traditional *Walker Process*-type exceptions for patent antitrust liability where the patent is fraudulently procured or the infringement action was a sham. *Id.* at 136.

The Federal Trade Commission's approach in *Schering-Plough*

In a decision heavily relied on by plaintiffs for its holding that exclusion payments exceeding litigation costs up to $2 million are prohibited under the Federal Trade Commission Act, the FTC also "question[ed] the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case."[12] *In re Schering-Plough Corp,* No. 04-10688, 2003 WL 22989651 (FTC Dec. 8, 2003) ("*Schering-Plough I*"), *set aside and vacated, Schering-Plough Corp. v. Federal Trade Comm'n,* 402 F.3d 1056, 2005 WL 528439 (11th Cir. Mar.8, 2005) ("*Schering-Plough II*").

The facts of that case involved two settlement agreements-one between Schering-Plough, the brand-name manufacturer of two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10, and Upsher, a generic manufacturer,

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12. The ruling was recently set aside and vacated by the Eleventh Circuit on other grounds (*i.e.,* not on the issue of the propriety of *post hoc* evaluations of a patent's validity).

and one between Schering-Plough and American Home Products ("AHP"), another generic manufacturer. *Id.* at 1065-1066. The Schering/Upsher agreement, entered on the eve of the parties' Hatch-Waxman patent infringement trial, called for Schering to make payments totaling $60 million to Upsher in exchange for, *inter alia*, Upsher's agreement not to enter the market with any generic version of K-Dur 20 for over four years. The Schering/AHP settlement, which also ended a Hatch-Waxman patent infringement trial, required Schering-Plough to make payments totaling $30 million in exchange for AHP's agreement not to market any generic version of K-Dur 20 for at least six years. *Id.* After rejecting Schering-Plough's argument that it had received any other consideration for its payments than Upsher's and AHP's agreements to delay marketing (both agreements included ancillary licenses), the FTC condemned the agreements as anti-competitive, but not on the basis of a *post hoc* review of the patents' validity.

The FTC provided a pragmatic reason for its refusal to assess validity, which had not been previously articulated by courts considering the issue:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the

> arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

Schering-Plough I, 2003 WL 22989651, at *19.[13]

Although the Eleventh Circuit heavily criticized the FTC for other aspects of its decision, it had no quarrel with the FTC's rejection of a *post hoc* analysis of patent validity, as its own analysis took no account of the potential invalidity of the patent. *Schering-Plough II*, 402 F.3d 1056, 2005 WL 528439.

This survey of the case law reveals that, with the possible exception of the Eleventh Circuit's instructions to the district court on remand in the *Valley Drug* case

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13. Plaintiffs here have raised a similar argument, suggesting that Barr's attorneys had developed a particularly strong attack on the '444 Patent that no subsequent challenger was capable of replicating. Indir. Pls.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V ("Indir. Pls.' Count V Opp'n"), at 2-4; Indir. Pls.' Mem. of Law in Opp'n to Generic Defs.' Mot. for Summ. J. and Bayer's Mot. for Partial Summ. J. on Pls.' Claims Under the Sherman Act and Corresponding State Law Claims ("Indir. Pls.' Sherman Opp'n"), at 13. Barr's patent counsel are undoubtedly fine attorneys, but it strains credulity to maintain that only one competitor's well-funded legal team could construct such a compelling case against the patent.

(*see* discussion *supra*), courts assessing the legality of patent settlement agreements have not engaged in a *post hoc* determination of the potential validity of the underlying patent (except in cases of *Walker Process* or sham litigation claims) when deciding whether an agreement concerning the patent violates antitrust law. These authorities are persuasive.

Above all, making the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether. Moreover, as explained *infra*, such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law.

In any event, although "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," *Valley Drug*, 344 F.3d at 1306, a *post hoc* assessment of the validity of the ciprofloxacin patent would likely do plaintiffs little good. After all, the '444 Patent has withstood multiple subsequent challenges and its validity has been affirmed by the Federal Circuit.[14] At oral argument, plaintiffs asserted that the court should give

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14. Indeed, there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit. Even the FTC's decision in *Schering-Plough* outlawing exclusion payments provided for prospective relief only. *Schering-Plough I*, 2003 WL 22989651, at *43.

little weight to these subsequent failed attacks because none of them raised what plaintiffs believe to be the most forceful attack on the '444 Patent-namely, inequitable conduct. Plaintiffs argue that this defense required extensive discovery and would take a long period of time to prepare and try, and that this explains why none of the subsequent challengers raised this issue.

But this argument is not very convincing in light of the fact that one of the challenges-Carlsbad's, on the ground of obviousness-also required extensive discovery and resulted in a nine-day bench trial. It is difficult to accept the notion that Carlsbad abandoned a stronger argument because it would have presumably required a greater effort, especially since Barr had already done most of the preparatory work on the inequitable conduct issue.

Plaintiffs further argue that the '444 Patent that emerged from reexamination in the PTO after Bayer's settlement with Barr was much changed from the '444 Patent that Barr had challenged, insinuating that the allegedly strong inequitable conduct defense that Barr had developed would be weaker, or possibly even unavailable, in the hands of challengers of the reexamined '444 Patent. Indir. Pls.' Count V Opp'n, at 3. This is clearly wrong, since the defense of inequitable conduct was available for all the '444 Patent's post-reexamination challengers. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed.Cir.1995) (affirming a finding of inequitable conduct, notwithstanding that the withheld reference was later cited during reexamination

and the claims were allowed to issue). Thus, the ability of the patent to withstand the subsequent challenges is persuasive, and the there is little likelihood that plaintiffs here would prevail in a *post hoc* attack on the patent.

In sum, it is inappropriate for an antitrust court, in determining the reasonableness of a patent settlement agreement, to conduct an after-the-fact inquiry into the validity of the underlying patent. Such an inquiry would undermine any certainty for patent litigants seeking to settle their disputes. In addition, exposing the parties to a patent settlement agreement to treble antitrust damages simply because the patent is later found to be invalid would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years. *Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351-52 (1965).[15]

ii. The effect of the possible invalidity of the patent on the legality of the Agreements

Having resolved that the validity of the '444 Patent should not be independently assessed, the next question that needs to be addressed is how the *possibility* that

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15. Indirect plaintiffs have added Count V to their complaint, alleging a state law *Walker Process*-type claim, namely that Bayer obtained the '444 Patent through fraud and that its suit against Barr was a sham litigation. These allegations are discussed more fully in connection with Bayer's motion to dismiss, *see infra* Part 3.

the patent is invalid should affect the legality of an exclusion payment. The heart of plaintiffs' argument is that there was at least a chance that the '444 Patent was invalid and, therefore, the Agreements violated antitrust law because the patent rights they enforce derive from a potentially invalid patent. They argue that the potential invalidity of the patent translates into a potential for open competition (and, hence, lower prices), and that the possibility of realizing such open competition was unfairly foreclosed by the Agreements.

Although plaintiffs do not attempt to litigate the validity of the '444 Patent in their motion for summary judgment, or in their opposition to defendants' motions for summary judgment, they do argue that the patent's potential invalidity should be taken into account when assessing whether the anti-competitive effects of the Agreements exceed the exclusionary scope of the patent. These arguments, plaintiffs assert, do not depend on an analysis of the '444 Patent's validity. In that regard, plaintiffs advance the reasoning of the FTC in *Schering-Plough,* now rejected by the Eleventh Circuit, and the views of several academics.

The starting point of the FTC's analysis whether the exclusion payments in that case were anti-competitive was to compare the amount of competition that occurred under the exclusion payment to "the amount of competition that was likely to occur had it not been for the payment . . . ." *Schering-Plough I,* 2003 WL 22989651, at *16. The FTC then examined and rejected Schering's defense that the restraint on trade

due to the exclusion payment was ancillary to the legitimate settlement of a patent dispute, reasoning that the amount of the payment ($60 million) was too high to be "a reasonably necessary element of a settlement that is procompetitive overall." *Id.* at 21. The FTC also rejected as implausible Schering's separate justification for the payment, that it was in exchange for some licenses. *Id.* at 40. The FTC concluded that the payment was made in exchange for delayed entry, and was therefore an agreement that "unreasonably restrains commerce." *Id.*

Plaintiffs note that the FTC relied on the economic analysis advocated by Professor Carl Shapiro in his article *Antitrust Limits to Patent Settlements,* 34 Rand J. Econ. 391 (2003), *see* Dir. Pls.' Summ. J.App., Tab 16, in which he states that, like litigants to a patent infringement suit, consumers have an "expected" gain from the patent challenge that equals their actual gains if the patent is invalidated, discounted by the probability of its being upheld. Dir. Pls.' Mem. at 14. The parties to the litigation, Professor Shapiro argues, should not be allowed to bargain away this assumed consumer surplus in reaching their settlement. Shapiro, 34 Rand J. of Econ. at 396 ("[A] patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Effectively, consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.").

This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer. *See, e.g., E. Bement & Sons v. Nat. Harrow Co.*, 186 U.S. 70, 91, 22 S.Ct. 747, 755, 46 L.Ed. 1058; *Studiengesellschaft Kohle*, 670 F.2d at 1127. Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants "to continue to litigate when they would prefer to settle" and "to act as unwilling private attorneys general and to bear the various costs and risks of litigation." *Nestle Co., Inc. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir.1985); *see also Times Mirror Magazines, Inc. v. Field & Stream Licenses Co.*, 103 F.Supp.2d 711, 741 (S.D.N.Y.2000) ("Insisting that a court review a settlement [of a trademark suit] to assure that no public confusion will result would make such agreements of little value to the parties . . . . Parties would sensibly conclude that they might better litigate the issue of confusion to conclusion rather than reach a settlement which might later be found to be unenforceable.") (quoting *T & T Mfg. Co. v. A.T. Cross Co.*, 449 F.Supp. 813, 827 (D.R.I.), *aff'd* 587 F.2d 533 (1st Cir.1978), *cert. denied*, 441 U.S. 908, 99 S.Ct. 2000, 60 L.Ed.2d 377 (1979)); Gen Defs. Opp. Mem. at 16 ("Plaintiffs' rule that

any of these settlements can be challenged by a third party claiming 'property rights' in some litigation outcome would increase the costs of litigation and of settlement by imbuing the entire process with an additional layer of uncertainty. Litigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued."). Although plaintiffs would no doubt argue that litigation is to be preferred in these drug patent cases, as pointed out in *Cipro II*, there is no support for the view that Hatch-Waxman intended to thwart settlements. *Cipro II*, 261 F.Supp.2d at 256.

Furthermore, even assuming some consumer surplus that the parties are bound to respect in settlement negotiations, such an interest would first have to be quantified. In seeking to calculate this consumer surplus, plaintiffs first couch their analysis in probabilistic terms, acknowledging this court's earlier admonishment that antitrust liability cannot be predicated on the possible outcome of litigation. Dir. Pls.' Mem. at 12-23; *Cipro II*, 261 F.Supp.2d at 202; *Schering-Plough I*, 402 F.3d, at 1074-1075, 2003 WL 22989651, at *16. In particular, plaintiffs argue that every patent has a chance of being held invalid, which should inure to the public's benefit. Dir. Pls.' Mem. at 12-23 (citing Shapiro, 34 Rand J. of Econ. at 395 ("[A] patent is best viewed as a *probabilistic* property right. What the patent grant actually gives the patent holder is the right to sue to prevent others from infringing the patent. Nothing in the patent grant guarantees that the patent will be

declared valid, or that the defendant in the patent suit will be found to have infringed.") (emphasis in original)).

To support this approach, plaintiffs resort to generalized statements about how patents fare in the courts. Dir. Pls.' Mem. at 18 ("Defendants themselves have admitted that, except in the rarest of cases, no patent stands a greater than 70% chance of being found to be valid."). This argument has some facial appeal, as it is common knowledge that many patents, once challenged, are ultimately held invalid and/or unenforceable. *See, e.g.,* Dir. Pls.' Summ. J.App., Tab 15 (John R. Allison and Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents,* 26 AIPLA Q.J. 185, 205 (1998) (showing that *533 nearly half of all litigated patents are found to be invalid)).

Ultimately, however, this argument proves too much. To begin with the premise, as characterized by generic defendants, that every patent is "a little bit invalid," results in undermining the presumption of validity that Congress has afforded patents. 35 U.S.C. § 282 ("A patent shall be presumed valid."); *see* Generic Defs.' Mem. in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J., at 9. Moreover, this premise could have far-reaching effects on everyday patent transactions. *See Schering-Plough II,* 402 F.3d at 1067, 2005 WL 528439, at *8 ("Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder.") (citing *Simpson v. Union Oil Co.,* 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964)). For example,

whenever a patentee and accused infringer enter a settlement (usually a license agreement), the accused infringer always either explicitly or implicitly acknowledges the patent's validity, and in many cases must pay the patentee a royalty if it wishes to continue selling the infringing goods.

Although plaintiffs contend that entry with a license is preferable to no entry at all, unless the license is royalty-free, the royalty itself is a barrier to entry, anathema to unfettered competition and, depending on the royalty rate, may offer minimal benefit to the public. If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty, a result that even Professor Shapiro would presumably disfavor. *See, e.g.*, Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. of Econ. at 395 ("[A] prohibition on settling patent disputes cannot make sense: as noted earlier, virtually every patent license can be viewed as the settlement of a patent dispute, and settlements generally can provide many benefits not only to the settling parties but to consumers as well."). To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries. *See In re Tamoxifen*, 277 F.Supp.2d at 137 ("No antitrust injury can flow from the prices at which Zeneca licensed

tamoxifen to Barr."); *see also Studiengesellschaft Kohle*, 670 F.2d at 1127.

Plaintiffs argue, as an alternative to the probabilistic method described above, that the potential invalidity of the patent can be inferred from the parties' behavior. Plaintiffs suggest that the settlement amount is evidence of the patent's fallibility because its value exceeds the litigation costs of fending off a challenge. Mem. of Dir. Pls. in Opp'n to Defs.' Mots. for Summ. J. at 45. Plaintiffs make the sensible argument that the higher the patentee's expectation of invalidity, the more it will be willing to pay a generic challenger to concede validity and stay out of the market. Thus, the very amount of the exclusion payment is evidence of the probable invalidity of the patent. Indeed, Bayer's own documents bear this theory out: a presentation slide prepared by Bayer's chief negotiator of the Bayer/Barr settlement contains the title, "The maximum settlement amount we should consider paying increases as the risk of losing increases." Dir. Pls.' Summ. J.App., Tab 47B, at BCP-P-0001668A-004. It is worth mentioning that the presentation slide in question includes a graph plotting Bayer's perceived risk of losing against various dollar amounts and that the amount Bayer ultimately paid Barr (approximately $398 million) is at the 20-25 percent risk-of-loss mark.[16]

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16. In fact, once the $398 million is converted to the then-net present value, the corresponding perceived risk of losing is even lower.

However, although direct plaintiffs contend that the amount of the exclusion payment in this case–$398 million-corresponds to a perceived chance of losing of about 50 percent, in absolute numbers Bayer's perceived chance of losing would appear to be much lower. How direct plaintiffs calculated this number is difficult to fathom,[17] especially since they cite Professor Hovenkamp's explanation of expected gains and losses in analyzing the anti-competitive effects of exclusion payments, who states: "[I]f the patentee has a 25% chance of losing, it is willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1759 (2003). Applying this model to Bayer's situation-plaintiffs submit that Bayer stood to lose more than $1.5 billion in profits if the '444 Patent was invalidated-reveals that Bayer's payment of $398 million translates to a perceived chance of losing of 26.5 percent. Of course, Bayer's payment to Barr was likely also constrained by the maximum amount Bayer expected Barr to make if it won the lawsuit, but applying a straight "expectation" economic analysis to these facts would indicate that Bayer was relatively confident of its chances of winning at trial.[18]

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17. As their expert candidly admits, "[t]he formulae underlying these calculations are complex." Dir. Pls.' Summ. J.App., Tab 33 (Expert Rep. of Keith B. Leffler, Ph.D., at 34 n. 85).

18. This absolute numbers "expectation" model is interesting, particularly in that it happens to line up with the (Cont'd)

Appendix C

Plaintiffs' point is well-taken that the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment. If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent,

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graph on Bayer's presentation slide, but there is no reason to rely upon it for an analysis of the legality of Bayer's payment to Barr. Moreover, this model may be overly simplistic, in that it does not account for other factors underlying the parties' negotiations, such as the possibility that subsequent challengers might enter the market for generic Cipro. In addition, both the indirect plaintiffs and the generic defendants asserted at oral argument that such a model should not be used in assessing the legality of the payment in this case. Indirect plaintiffs argue that a better measure of Bayer's perceived chances of winning the litigation against Barr could be extrapolated from a comparison of the actual payment to Barr's anticipated profit had it won the litigation. Generic defendants, on the other hand, accept that the expectation model could be used to approximate Bayer's perceived chances of success, but assert that the legality of the payment depends not on Bayer's subjective perception of its chances, but rather only on whether the patent litigation was a sham.

whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. *See, e.g.*, Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L.Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing."). Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. *Cf. id.* at 25 n. 54 (noting "ample history of litigation among large numbers of rivals being settled with a comprehensive licensing agreement," but acknowledging that those settlements "typically did not involve exit payments, but rather cross-licenses"). It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.[19] *See, e.g., Andrx Pharma., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 814 (D.C.Cir.2001) ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may

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19. A similar argument could be constructed for situations, unlike the one here, where infringement is the dominant issue in the underlying patent litigation. If the scope of the claims is in dispute, but arguably narrow enough that not every bioequivalent generic drug would infringe the patent, it could be expected that additional generic challengers would be spurred to design around the patent and file their own ANDA IVs based on non-infringement.

temporarily possess it. 'Existing firms know that if they collude or exercise market power to charge supracompetitive prices, entry by firms currently not competing in the market becomes likely, thereby increasing the pressure on them to act competitively.' ") (quoting *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 717 n. 13 (D.C.Cir.2001)).

Plaintiffs counter that such a market correction would have no impact on the injury to the market in the period before a subsequent challenger successfully invalidates the patent. But that is true in the case of all patents, not just pharmaceutical patents. Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent. *Cf. Schering-Plough II*, 402 F.3d at 1066-1067, 2005 WL 528439, at *8 ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent."). More significantly, this type of delay is entirely within the control of the would-be subsequent challengers, who alone decide when they will challenge the patent by filing an ANDA IV.[20]

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20. Barr filed its ANDA IV on the first day it was permitted to do so under 21 U.S.C. § 355(j)(5)(D)(ii). *See Cipro II*, 261 F.Supp.2d at 194. There was no legal bar to other generics filing

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Plaintiffs further argue that the very fact that Bayer made an exclusion payment evidences the anti-competitive nature of the Agreements because a brand-name manufacturer's exclusion payments "eliminate its expected losses under litigation-and therefore eliminate consumers' expected gains under litigation . . . ." Dir Pls.' Mem. at 17. Plaintiffs again point to the FTC's decision:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

Schering-Plough I, 402 F.3d, at 1074-1075, 2003 WL 22989651, at *16. The problem with this argument is that, due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a

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ANDA IVs that same day or any day thereafter, although pragmatic and economic considerations may have influenced their decision to wait at least until Barr's challenge had concluded before launching their own attacks on the '444 Patent. This is because if Barr were successful, the marketing approval for other generics would be withheld until Barr's 180-day exclusivity period expired.

reasonable litigation compromise for early (pre-patent expiration) entry by the generic challenger. The FTC acknowledges that "[t]he anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." *Id.* Thus, for each day of early (royalty-free) entry by the generic challenger, the brand-name manufacturer will lose many times more in expected profits than the generic challenger will gain. This is, of course, the reason why brand-name manufacturers make exclusion payments rather than granting a license. There simply is no otherwise reasonable litigation compromise.

Moreover, plaintiffs' assertion that Bayer's payment to Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement must also fail. This assertion ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable. *See, e.g., Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko, LLP,* 540 U.S. 398, 415-16, 124 S.Ct. 872, 883, 157 L.Ed.2d 823 (2004) ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). In sum, Bayer and Barr cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did

reach does not adversely affect competition beyond the scope of the '444 Patent.[21]

Finally, plaintiffs argue that Congress granted only a rebuttable presumption of validity, not a conclusive presumption, and that by making a payment, Bayer is buying that which Congress declined to grant. This argument was explicitly rejected by the Eleventh Circuit in *Valley Drug:*

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21. Candor requires that I recognize that this conclusion is, to some extent, inconsistent with the view expressed in *Cipro I* regarding the motions to remand, where the opinion stated:

> A review of [plaintiffs'] allegations makes plain that plaintiffs have asserted at least one theory by which they may establish state antitrust violations without resorting to a determination of patent law. Plaintiffs' complaints allege there would have been generic competition in the market for ciprofloxacin prior to the expiration of Bayer's patent if Bayer had not reached an unreasonably anti-competitive agreement with Barr, HMR, and Rugby ... [Plaintiffs] asserted that, as a matter of fact, Bayer would have authorized Barr to distribute ciprofloxacin by granting Barr a license, or by other means, had Barr not agreed to drop its challenge to the validity of the '444 patent in exchange for large cash payments.

Cipro I at 748.

Upon further reflection, I have concluded that patent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.

> We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.

Valley Drug, 344 F.3d at 1309.

The FTC held that the Schering-Plough exclusion-payment patent settlements violated Section 5 of the Federal Trade Commission Act, *Schering-Plough I*, 2003 WL 22989651, at *43, but specifically exempted from antitrust scrutiny settlements involving only an early entry date. *Id.* at 19 ("Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack."). The difficulty with this approach is that it is not clear that consumers would benefit more from such an arrangement than from an exclusion-payment settlement like the one here. Presumably, the parties to a Hatch-Waxman patent litigation could settle

on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment. In response to questions on this point at oral argument, indirect plaintiffs and generic defendants agreed that some sort of license, such as an exclusive license for a limited geographic area, "theoretically" could have been negotiated that would, as between the parties, approximate the effect of an exclusion payment. Indir. Pls.' Resp. to the Court's Questions, at 3; Gen. Defs.' Resp. to the Court's Feb. 22, 2005 Questions, at 4. Bayer and Barr, however, focused as they were on defeating plaintiffs' theory that, absent the payment, Bayer and Barr would have agreed on an earlier entry date, were reluctant to concede the point. As Professor Hovenkamp points out,

> In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and simply 'licensing' another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of them would be paid as license fees rather than as markup on goods that it produced. If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would

> license some output to a rival, earning the monopoly profits as royalties. Assuming zero transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all.

Hovenkamp, 87 Minn. L.Rev. at 1750-51.

Assuming the soundness of Professor Hovenkamp's analysis (and it is hard to see how it can be contested), if the monopolist's profit margins are extraordinarily high, the royalty on an early-entry license could be so high that the generic company's prices would be no lower than the brand-name manufacturer's. In this case, given Bayer's projected price drop of 95 percent a year in the future, it is reasonable to infer that Bayer's profit margin for Cipro was in excess of 95 percent.[22] In fact, plaintiffs concede that the terms of Bayer's six-month license to Barr called for an 85 percent royalty, but they complain that the license did not benefit consumers because the royalty was so high. Indir. Pls.' Sherman Opp'n, at 26. Indeed, indirect plaintiffs argue that a drug can only be considered "generic" if it is priced at least at a ten percent discount to its branded counterpart at

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22. Indirect plaintiffs also allege in their pleadings that Bayer maintained an exceptional profit margin for Cipro: "Bayer's 1999 United States gross sales of Cipro were approximately $1.04 billion and its net sales (or profits) were in excess of $920 million." Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 70.

the end-payer level, a standard that was not met by Barr's selling price under the six-month license from Barr, because the 85 percent royalty was paid at the wholesale, not retail, level. Thus, outlawing exclusion-payment settlements in favor of early-entry licenses would not necessarily result in a public benefit or satisfy plaintiffs, unless royalty rates are also constrained. Such constraints on patent holders are, of course, impermissible. *See, e.g., E. Bement & Sons,* 186 U.S. at 91, 22 S.Ct. at 755 ("[T]he general rule is absolute freedom in the use or sale of rights under the patent laws of the United States.... The fact that the conditions in the contracts [for patent licenses] keep up the monopoly or fix prices does not render them illegal."); *Studiengesellschaft Kohle,* 670 F.2d at 1127 ("A patentee has the right to exclude others from profiting from the patented invention. This includes the right to suppress the invention while continuing to prevent all others from using it, to license others, or to refuse to license, and to charge such royalty as the leverage of the patent monopoly permits.") (citations omitted).

And even if royalty rates were suppressed so as to preserve some consumer benefit, at some point the interests of the patent holder and the generic would diverge so that settlement would be impossible and continued litigation the only viable course. While plaintiffs may view this as a desirable outcome, as noted, the Eleventh Circuit vacated and set aside the FTC's opinion in *Schering-Plough* as inconsistent with the Eleventh Circuit's holding in *Valley Drug* that "[s]imply because a brand-name pharmaceutical company holding

a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law," unless the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." *Schering-Plough*, 402 F.3d at 1076, 2005 WL 528439, at *17.

A significant issue before the FTC was Schering's affirmative defense that the agreements to delay entry were ancillary to the legitimate settlement of a patent dispute. *Schering-Plough I*, 2003 WL 22989651, at *9, 20. Before measuring the anti-competitive impact of the agreements against the scope of the patent, the Eleventh Circuit reviewed the FTC's determination that Schering's payments to the generic companies were not *bona fide* royalty payments under the licenses Schering obtained from the generics, noting that "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay [in the generics entering the market]." *Id.*, 402 F.3d at 1068, 2005 WL 528439, at *10. After rejecting the FTC's determination as "not supported by law or logic," the Eleventh Circuit then characterized the aspect of the agreements dealing with the delay in generic marketing as "ancillary restraints" which are "secondary and collateral*539 to an independent and legitimate transaction." *Id.*, 402 F.3d at 1073, 2005 WL 528439, at *14. Noting that such ancillary restraints "are generally permitted if they are reasonably necessary toward the contract's objective of utility and efficiency," the Eleventh Circuit found that the delay provisions were appropriately narrow, as they reached only products that were covered by Schering's patent. *Id.*

Plaintiffs point to the Eleventh Circuit's lengthy discussion of whether the payments were *bona fide* royalty payments as a disavowal of a rule that any payment from the patent holder for a competitor's exclusion that is within the scope of the patent is exempt from antitrust scrutiny. Letter from Steve D. Shadowen dated 3/15/2005, at 2-3. Instead, plaintiffs view that discussion as expressing agreement with plaintiffs' position that such payments in exchange for delay do in fact exceed the scope of the patent. *Id.* A more plausible explanation for the Eleventh Circuit's in-depth treatment of the bona fide royalty question is that the discussion framed the issue of whether the delay aspects of the agreements were ancillary restraints or not. Indeed, the Eleventh Circuit's endorsement of a rule permitting exclusion payments that do not exceed the scope of the patent could hardly be clearer:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. An exception cannot lie . . . when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements). The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall

> within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

Schering-Plough II, 402 F.3d at 1075-1076, 2005 WL 528439, at *17 (citations and internal quotation marks omitted).

Plaintiffs also argue that the Eleventh Circuit's concluding admonition that there is a need "to evaluate the strength of the patent," *Schering-Plough II*, 402 F.3d at 1076, 2005 WL 528439, at *17, bolsters plaintiffs' argument that the potential invalidity of the '444 Patent should be taken into account when measuring the exclusionary scope of the patent. Letter from Joseph Lipofsky dated 3/14/2005, at 1-2. In the context of both the opinion as a whole and the controlling precedent of *Valley Drug*, this admonition is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity, an approach which, as discussed *supra* at Part (1)(b)(i), has not been endorsed by any court other than the *Valley Drug* district court on remand.

To summarize, it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity.[23] Nor is it appropriate to discount the

23. Of course, as previously discussed, such an inquiry would hardly redound to plaintiffs' benefit, given that the '444 Patent has already been upheld by the Federal Circuit once, that three other attacks have failed and that only a speculative attack is proposed by the plaintiffs here. *See supra* Part 1(b)(i).

exclusionary power of the patent by any probability that the patent would have been found invalid. Moreover, the FTC's now-vacated rule that exclusion payments beyond litigation costs are always illegal should be rejected because it ignores the justified needs of the patent holder in the face of the risks of litigation, especially in an arena where it is well-known that courts are far from error-free.[24] The test for determining the validity of the so-called reverse or exclusion or exit payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims. Here, the only serious argument plaintiffs have raised in that regard is possible manipulation of the 180-day exclusivity period by Barr.

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24. At least two commentators have suggested that, "[f]or purposes of antitrust analysis, there are and can be no 'wrong' decisions reached by courts in patent litigation . . . [because] [t]he substantive rights granted by Congress to patent holders are those rights . . . which a federal court determines, through congressionally prescribed process, that the patent holder possesses. Because there are no 'wrong' results generated by the patent litigation process, the patent holder improperly enlarges the innovation reward granted to him by Congress when he buys 'insurance'–in the form of exclusion of a competitor–against a 'wrong' result in the patent litigation." Keith B. Leffler and Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 ABA Economics Committee Newsletter 26 (Spring 2002). The fallacy of this argument is that it leads to the inevitable conclusion that it is always improper for a patentee to insure against an unfavorable result by paying for a competitor's exclusion. All hedging by patentees-that is, all patent settlements-are now suspect.

However, the theory was fully briefed and disposed of in the *Cipro II* decision and need not be decided anew here. *Cipro II*, 261 F.Supp.2d at 243-47. In short, Barr's amendment of its ANDA IV to an ANDA III cleared the way for subsequent generic companies to mount challenges to the '444 Patent, an eventuality that was borne out. At least four generic companies filed ANDA IVs after Bayer and Barr entered the Agreements, so it cannot be reasonably argued that the Agreements created a bottleneck to future generic challenges.

Plaintiffs complain that they have been doubly harmed by the Agreements: first by the exclusion of Barr from the market, and second by Bayer's passing on the cost of the settlement payment in the form of increased prices for Cipro. However, if the Agreements themselves do not exceed the exclusionary power of the '444 Patent, any increased prices resulting from the Agreements are the result of the monopoly inherent in the patent. Indeed, "an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Studiengesellschaft Kohle*, 670 F.2d at 1128 (citing *Brulotte v. Thys Co.*, 379 U.S. 29, 33, 85 S.Ct. 176, 179, 13 L.Ed.2d 99 (1964) (dictum); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136, 89 S.Ct. 1562, 1583, 23 L.Ed.2d 129 (1969)). Of course, market forces may impose some limits on the prices a patentee can charge. At some point, additional competitors will be spurred to either challenge the patent or design around it, or consumers will find a more affordable (although perhaps less desirable) alternative. *See, e.g., Andrx v. Biovail*, 256 F.3d at 814.

To conclude, in the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Because plaintiffs have not shown that the Agreements had anti-competitive effects beyond the scope of the '444 Patent, it is not necessary to address the second and third steps of the rule-of-reason analysis–whether defendants can establish the "pro-competitive redeeming virtues" of the Agreements, and whether plaintiffs can "show that the same pro-competitive effect

could be achieved through an alternative means that is less restrictive of competition." *K.M.B. Warehouse*, 61 F.3d at 127.

(2)

Consumer Antitrust Standing

As the law now stands, the validity of a patent may be challenged only by an alleged infringer as an affirmative defense or counterclaim to an infringement action brought by the patentee, or by a declaratory judgment plaintiff, who must show

> (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.

Teva Pharma. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1330 (Fed.Cir.2005). Therefore, at present, non-infringing consumers of patented products who may feel that they are being charged supracompetitive prices by the patentee have no cause of action to invalidate the patent.

It is also apparent that Congress did not intend to change the standing requirements for actions to invalidate patents when it passed, and still more clearly when it later amended, the Hatch-Waxman Amendments in 2003. *See* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat.2066, entitled "Access to Affordable Pharmaceuticals" ("Medicare Amendments"). Indeed, in the Medicare Amendments, which were passed on December 8, 2003, after the issues revolving around exclusion-payment and other settlements between brand-name manufacturers and generics had already surfaced, Congress provided for explicit forfeiture of the 180-day exclusivity period that would otherwise be enjoyed by the first filer of an ANDA IV if the first filer settles its suit with the brand-name manufacturer, but only if the Federal Trade Commission or the Attorney General obtains a final decision from the Federal Trade Commission or a court that the agreement between the first filer and the brand-name manufacturer has violated the antitrust law. *See* 21 U.S.C. 355(j)(5)(D)(i)(V) (Supp.2004).[25] Notably,

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25. The subsection reads

> **(V) Agreement with another applicant, the listed drug application holder, or a patent owner**
>
> The first applicant [forfeits its 180-day exclusivity period if it] enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of

(Cont'd)

Congress made no provision for loosening the standing requirements for challenging patents or even for forfeiture of the 180-day exclusivity period where the antitrust complaint is brought by consumers.

Given that consumers are often subjected to monopoly prices for invalid patents, it is tempting to suggest that, as a policy matter, a rule should be fashioned giving consumers of drugs-and perhaps patented goods generally–the right to challenge the validity of patents. In other words, plaintiffs should be afforded the opportunity to challenge the exclusion-payment scheme at issue here-and licensing arrangements as well-by folding in a predicate challenge to the underlying patent itself. Under the proposed rule, the consumers would have to show by clear and convincing evidence–as accused infringers must-that the subject patent was invalid. This proposal would have the effect of allowing non-infringing consumers of a

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(Cont'd)

> the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

patented product to seek to invalidate the patent in order to allow price-reducing competitors to enter the market. The desirability of such a change is a complex issue which is not within the competence of judges. A thorough examination of the consequences of such a change would have to be made. For example, would such a change negatively impact the willingness of drug manufacturers to invest in research and development? Should consumers be permitted to recover punitive damages for the overcharges they have suffered? As Justice Harlan noted, patents are often set aside for any number of technical reasons. *Walker Process,* 382 U.S. at 179-80, 86 S.Ct. at 351-52. Perhaps permitting only declaratory relief, together with attorneys' fees, would solve the problem of unduly punishing those who in good faith sought patents that ultimately were shown to be invalid. Another possible alternative is to limit the consumer recovery to the amount of the monopolistic overcharges. These questions lead to the inevitable conclusion that such a change in public policy should be made by Congress, and not by the courts.

(3)

Bayer's Motion to Dismiss Count V of Indirect Plaintiffs' New Complaint

Recognizing that the ultimate vindication of the '444 Patent might immunize the Agreements from antitrust scrutiny under the rule of reason, indirect plaintiffs amended their complaint to add charges that would strip Bayer of its patent immunity. Indir. Pls.' Mem. of Law

in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V, at 1. Six months after summary judgment motions were decided in *Cipro II*, indirect plaintiffs moved to amend their complaint to add claims that Bayer violated state antitrust and/or consumer protection laws by virtue of alleged inequitable conduct before the PTO in procuring the '444 Patent and alleged sham litigation in enforcing the '444 Patent against Barr. Indir. Pls.' Second Am. Consol. Class Action Compl., ¶¶ 296-308. The substance of this new count of the complaint, Count V, is that Bayer made a series of misrepresentations to the PTO in order to secure issuance of the '444 Patent, and then, with knowledge that the patent was invalid and had been fraudulently procured, asserted the patent against Barr even though no reasonable litigant in Bayer's position "at the time of its settlement with Barr" could have expected to win the litigation. Indir. Pls.' Second Am. Consol. Class Action Compl., ¶ 305. Bayer moves to dismiss Count V on two threshold grounds: that it is preempted by federal patent law and barred by the statute of limitations.

Ordinarily, antitrust claims premised on the enforcement of a fraudulently procured patent are brought by an accused infringer as a counterclaim to the original charge of infringement. *See, e.g., Nobelpharma,* 141 F.3d at 1067 ("[A]n antitrust claim premised on stripping a patentee of its immunity from the antitrust laws is typically raised as a counterclaim by a defendant in a patent infringement suit.") Indirect plaintiffs' claims are unusual, both because they are brought by indirect purchasers of the patented item and

because they are asserted under state law. Whatever the reasons for indirect plaintiffs bringing *Walker Process* and sham litigation claims under state law, those claims are preempted by federal patent law and must, therefore, be dismissed.

28 U.S.C. § 1338(a) grants federal district courts exclusive jurisdiction over "any civil action arising under any Act of Congress relating to patents . . . ." Thus, if indirect plaintiffs' state law *Walker Process* and sham litigation claims "arise under" patent law, they may only be heard in federal court.[26] The Supreme Court elucidated what it means for a claim to "arise under" patent law in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809-11, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988). Under the well-pleaded complaint rule, plaintiffs' claim must be judged solely on the face of the complaint, without reference to any anticipated defenses; unless patent law is necessary to each and every theory under the claim, § 1338(a) jurisdiction will not be invoked. *Id.*

Here, indirect plaintiffs' Count V rests entirely on patent law. If indirect plaintiffs cannot prove that Bayer

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26. Although the fact that a state law cause of action may only be heard in federal court does not necessarily mean that it is preempted by federal law, *see Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1334 (Fed.Cir.1998), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358-59 (Fed.Cir.1999), the inquiries are closely related and in certain circumstances do overlap.

intentionally withheld or misrepresented material information to the PTO during prosecution of the '444 Patent, their *Walker Process* and sham litigation claims cannot survive. Specifically, "[a] finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. . . . [and] must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1070-71. There is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO. Furthermore, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Id.* at 1068 (*en banc* in relevant part). And while sham litigation could theoretically be shown by assertion of a patent known to be valid but not infringed, such a theory is not available in this case, where Barr admitted infringement, not just as part of the post-settlement consent judgment, but in the July 25, 1996 Stipulation and Order, entered long before the Agreements were ever negotiated. *See* Bayer Sherman Act App., Ex. 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)). Indeed, Barr never contested infringement of the '444 Patent, even in its December 6, 1991 Paragraph IV detailed statement which triggered the Bayer/Barr patent litigation. Bayer Sherman Act App., Ex. 2.

The fact that indirect plaintiffs' Count V not only arises out of patent law, but rests entirely on patent law, leads to two conclusions. First, jurisdiction over Count V lies exclusively in federal court. 28 U.S.C. § 1338(a); *Christianson,* 486 U.S. at 809-11, 108 S.Ct. 2166; *cf. Cipro I,* 166 F.Supp.2d at 750-51 (holding that remand was appropriate where plaintiffs had "pleaded at least one theory under which their claims for relief may be resolved without determining the validity of Bayer's patent"); *but see Williams v. Del Monte Fresh Produce Co.,* 325 F.Supp.2d 855, 858-60 (M.D.Tenn.2004) (remanding to state court state law claims predicated on fraudulent procurement and enforcement of a patent, where patentee admitted invalidity of patent, thus obviating the need for the state court to adjudicate the federal question). Second, federal patent law preempts any state antitrust cause of action premised on Bayer's alleged bad faith conduct before the PTO because Count V does not allege any conduct other than conduct before the PTO. In other words, the state law remedies invoked by indirect plaintiffs are directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace. *Cf. Hunter Douglas,* 153 F.3d at 1334; *Dow Chem. Co. v. Exxon Corp.,* 139 F.3d 1470, 1477 (Fed.Cir.1998).

Indirect plaintiffs' Count V allegations parallel the abuse of process counterclaim brought in *Abbott Labs. v. Brennan,* 952 F.2d 1346 (Fed.Cir.1991). There, the Board of Patent Appeals and Interferences awarded priority of invention in an interference proceeding to Brennan, even though Abbott had first conceived and

reduced the invention to practice because Abbott's attorney had backdated a request for extension of time and falsely averred that the request had been timely made. *Id.* at 1348. Abbott brought a civil action in district court seeking to set aside the award of priority to Brennan, and Brennan counterclaimed for, *inter alia,* the state law tort of abuse of process. The Federal Circuit reversed the judgment of abuse of process, concluding "that the federal administrative process of examining and issuing patents, including proceedings before the PTO's boards, is not subject to collateral review in terms of the common law tort of abuse of process." *Id.* at 1357. The court reasoned that "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO, 'under the guise of a complaint sounding in tort,' ... and is contrary to Congress' preemptive regulation in the area of patent law." *Id.* (quoting *Gilbert v. Ben-Asher,* 900 F.2d 1407, 1411 (9th Cir.1990)).

The allegations of Count V differ from the state law claim for unfair competition that was not preempted by federal law in *Dow.* There, Dow alleged that Exxon had threatened to sue actual and prospective Dow customers for patent infringement, even though Exxon allegedly had no good-faith belief that Dow infringed the patent when Exxon made the threats and had allegedly obtained the patent by inequitable conduct. *Dow,* 139 F.3d at 1472. The court held that the claim was not preempted because the tort claim was "not premised upon bad faith misconduct in the PTO, but rather [was] premised upon bad faith misconduct in the

marketplace." *Id.* at 1477. The marketplace misconduct in *Dow* was Exxon's threats to Dow's customers,*545 not activity that occurred before the PTO or in the context of a litigation. *Id.* at 1472. Indirect plaintiffs' Count V does not allege any malfeasance in the marketplace such as threats to Barr or its customers, but instead rests entirely upon actions that occurred before the PTO. Because the allegations of Count V are coextensive with patent law, they are preempted by patent law. *See, e.g., Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd.*, 204 F.3d 1368, 1382 (Fed.Cir.2000) (affirming dismissal of state RICO counterclaims that "occupy a field identical in scope with the inequitable conduct defense," and noting that "[a]n additional state cause of action predicated so squarely on the acts of inequitable conduct would be 'contrary to Congress' preemptive regulation in the area of patent law.' ") (quoting *Abbott*, 952 F.2d at 1357).[27]

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27. Indirect plaintiffs point to a number of cases in which state law causes of action predicated on bad faith procurement of patents have been allowed to go forward. Those cases do not alter the analysis, as none of them addresses preemption of state law *Walker Process* or sham litigation claims. For example, *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D.Mass.2004), deals with class certification issues, and makes only passing reference to one allegation that the defendants "entered the market under the banner of a patent procured by fraud." *Id.* at 266. The court's analysis was limited to a determination of whether the requirements of Rule 23 were met, and it did not consider the merits of the case. *Id.* at 265. In subsequent opinions, the *Relafen* court clarified that the indirect plaintiffs in that case were pursuing their *Walker Process* claims as

(Cont'd)

Appendix C

The only conduct not directly referable to the PTO that indirect plaintiffs point to as an instance of marketplace "maintenance" of the '444 Patent is Bayer's compulsory listing of the '444 Patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," or the "Orange Book," as required under 21 U.S.C. § 355(b)(1). Indir. Pls.' Second Am. Consol. Class Action Compl., ¶ 243;

(Cont'd)
assignees of the rights of several national wholesalers (*i.e.*, direct purchasers), and their claims were therefore not barred by *Illinois Brick*. *See In re Relafen Antitrust Litig.*, 346 F.Supp.2d 349, 368 (D.Mass.2004); *In re Relafen Antitrust Litig.*, 2005 WL 418086, at *17, *21 (D.Mass. Feb.22, 2005). Significantly, none of the *In re Relafen* opinions discusses whether state law *Walker Process* claims are preempted. In both *Intel Corp. v. Via Techs., Inc.*, 2001 WL 777085, at *6 (N.D.Cal. Mar.20, 2001) and *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F.Supp.2d 540, 549 (D.N.J.2000), district courts allowed state law claims to proceed where the only ground on which the parties moved to dismiss was that the state law claims were dependent on the survival of related federal antitrust claims, which were not dismissed. Similarly, in *FDI, Inc. v. W.R. Grace & Co., Inc.*, 1980 WL 1996, *3-4 (C.D.Cal. Sept.29, 1980), the court refused to grant summary judgment on portions of plaintiff's federal *Walker Process* antitrust and related unfair competition claim based on the same allegations, although preemption is not discussed in the opinion. Thus, although indirect plaintiffs have cited several cases in which state law claims based at least in part on misconduct before the PTO have been permitted to proceed, they have at least to some extent involved non-PTO conduct. In any event, none of them is binding precedent, and none of them cites any reason why such claims are not preempted by federal patent law.

Indir. Pls.' Responses to the Court's Questions for Oral Argument, 2/28/2005. They cite *In re Buspirone Patent Litig.*, 185 F.Supp.2d 363, 369-73 (S.D.N.Y.2002), in support of the proposition that such Orange Book filings can be used as a basis for a state law action. The issue before the court in *Buspirone* was whether the Orange Book filings were protected activity under the *Noerr-Pennington* doctrine. *See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). The district court held that the filings were not protected under *Noerr-Pennington*, but did not say one way or the other whether Orange Book listings constitute marketplace activity subjecting patent holders to state law antitrust remedies where the underlying alleged bad-faith conduct occurred before the PTO.

Even were one to assume that the Orange Book filing of the '444 Patent would provide a basis for a state law claim, this would not advance plaintiffs' cause here. There was nothing in the act of listing the '444 Patent in the Orange Book that was itself improper, *cf. In re Buspirone*, 185 F.Supp.2d at 369-73, and the filing, according to plaintiffs, was only improper because Bayer was using it to maintain an allegedly ill-gotten patent. But this claim in turn depends first on a showing that the '444 Patent was obtained by fraud on the PTO.

Plaintiffs cannot by this collateral or backdoor method avoid preemption of their state law claim.[28]

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28. Assuming that the mere listing in the Orange Book constituted marketplace misconduct, it is highly unlikely that indirect plaintiffs would be able to establish a *Walker Process* claim. Initially, *Walker Process* fraud requires a showing that the omission or misrepresentation to the Patent Office was so material that the patent would not have issued but for the omission or misrepresentation (a level of materiality referred to as "but for" materiality); consequently, a patent must be invalid before it can be a candidate for *Walker Process* fraud. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1365 (Fed.Cir.1998) ("Indeed, since the inventorship issue was not grounds of invalidity, it can not satisfy the "but for" test of fraud."); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed.Cir.1998) ("Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an *invalid* patent.") (emphasis added). In contrast, because the patent litigation defense of inequitable conduct does not require so high a level of materiality, it is possible for a patent to be unenforceable for inequitable conduct, but still valid. *See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1237 (Fed.Cir.2003) (citing *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed.Cir.2000)). Indirect plaintiffs' reliance on *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed.Cir.2004) for the proposition that the materiality requirement for a showing of *Walker Process* fraud is met by simply pointing to the PTO's issuance of a patent is a gross misreading of the law. First, *Unitherm* did not depart from the standard set forth in *Nobelpharma* for showing "but for" materiality, and concluded: "Had the PTO not relied on this fraud, the Examiner would have reached the same conclusion as did the district court and this court . . . that no

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Furthermore, indirect plaintiffs cite eight instances of improper conduct before the PTO. Some have already been rejected by Judge Brewster as failing to establish invalidity (*see Bayer AG v. Carlsbad Tech., Inc.*, No. 01-cv-0867-B, slip op. at 6-7 (S.D. Cal. June 7, 2002)), some by the PTO during reexamination (Bayer Pat.App. Ex. 9) and others have been conceded as not rising to the level of "but for" materiality. More importantly, indirect plaintiffs did not adduce evidence of "but for" materiality for seven of these instances. The only instance for which their expert opined "but for" materiality was a claim that Bayer's statements regarding the superiority of the "compounds of the invention" to the prior art was misleading, because Bayer withheld data showing that certain of the claimed compounds were not, in fact, superior to the prior art. Lawyer advocacy or puffery is not a basis for granting or denying a patent claim. Superiority is not the issue. What is required instead is a showing of novelty and non-obviousness for a patent to issue, 35 U.S.C. §§ 102, 103, and for that the patent examiner is presumed to have relied on data, not attorney advocacy. *Cf. CFMT,*

(Cont'd)

valid patent could issue from [the] application." *Unitherm*, 375 F.3d at 1361 (emphasis added). Second, if plaintiffs' assertion were correct-that simple issuance of a patent is sufficient to prove "but for" materiality-then the standard for proving *Walker Process* fraud materiality would be lower than the showing required for inequitable conduct and would, in fact, be met in every case. Such a conclusion is directly contrary to the Federal Circuit's holding in *Nobelpharma* and is not supported by *Unitherm.*

Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1342 (Fed.Cir.2003) ("During prosecution, an applicant may submit objective factual evidence to the PTO in the form of patents, technical literature, and declarations . . . . The advantages advocacy in this case does not fit any of these categories and was unaccompanied by and not asserted to be supported by any factual evidence. Therefore, a reasonable examiner would not have found it important in deciding whether to allow the application.")

Even if plaintiffs had made a sufficient showing of marketplace misconduct by Bayer in enforcing its '444 Patent to create an issue of fact, there is a serious question whether indirect plaintiffs have standing to assert a *Walker Process* claim. In *Asahi Glass,* Judge Posner, in *dicta,* assumed that a *Walker Process* claim is only available to a patentee's competitors. *Asahi Glass,* 289 F.Supp.2d at 995 ("The claim of fraud on the patent office fails for the reason just given: if patent 723 was obtained by fraud, it was a fraud aimed at competing manufacturers of drugs, not at the suppliers of those manufacturers, and so the fraud claim cannot be pressed as an antitrust claim."). This view was earlier expressed by Judge Markey, later of the Federal Circuit, sitting by designation in *Oetiker v. Jurid Werke GmbH,* 671 F.2d 596, 599 (D.C.Cir.1982) ("The Supreme Court has established that one guilty of fraudulent procurement and attempted enforcement of the patent thus procured may be liable for treble damages to *competitors* under the antitrust laws.") (citing *Walker Process,* 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247)

(emphasis added). *See also In re Remeron Antitrust Litig.*, 335 F.Supp.2d 522, 529 (D.N.J.2004) ("*Walker Process* and its progeny involve antitrust counterclaimants who were potential or actual competitors in patent infringement suits. In this case, Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.").

Finally, Bayer moves for summary judgment that Bayer's suits against Barr and the subsequent '444 Patent challengers were not sham litigation as a matter of law. To prove sham litigation, a plaintiff must show (1) "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) that the litigant's "subjective motivation" for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61, 113 S.Ct. 1920, 1928, 123 L.Ed.2d 611 (1993). Here, Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams. *See id.*, 508 U.S. at 61 n. 5, 113 S.Ct. at 1928 n. 5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Indirect plaintiffs' argument that Bayer's successes in the post-Barr litigations are immaterial, since the '444 Patent had by then undergone

reexamination, is unconvincing. As discussed *supra*, reexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers. *Molins v. Textron*, 48 F.3d at 1182.

In any event, as Bayer's motion to dismiss Count V is granted on the preemption ground, it is not necessary to reach the question of whether indirect plaintiffs' state law *Walker Process*-type claims and sham litigation claim are barred by the statute of limitations.

Conclusion

Applying a rule of reason analysis, the first element antitrust plaintiffs must prove is that the challenged agreements had an actual adverse effect on competition in the relevant market. Here, plaintiffs have failed to demonstrate anti-competitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the '444 Patent. The '444 Patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims. This result is compelled by the presumption of validity Congress accorded patents and the destabilizing effect on patent law that a contrary decision would work. Any readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts.

For the foregoing reasons,

- Bayer's Motion for Partial Summary Judgment on Plaintiffs' Claims Under the Sherman Act and Corresponding State Law Claims is granted;

- Generic Defendants' Motion for Summary Judgment is granted;

- Direct Purchaser Plaintiffs' Motion for Partial Summary Judgment is denied;

- Bayer's Motion to Dismiss Count V of the Indirect Purchaser Complaint Based on Threshold Grounds is granted;

- Bayer's Motion for Partial Summary Judgment on Count V of the Indirect Purchaser Class Plaintiffs' Proposed Second Amended Consolidated Class Action Complaint is dismissed as moot;

- HMR and Rugby's motion for summary judgment is dismissed as moot;

- Direct plaintiffs' amended complaints are dismissed;

- Indirect plaintiffs' second amended consolidated class action complaint is dismissed;

- Plaintiffs' motions for class certifications are denied as moot.

The Clerk of the Court is directed to close this case.

Dated: Brooklyn, New York

March 31, 2005

SO ORDERED:

David G. Trager

United States District Judge

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND FILED DECEMBER 23, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1097

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE PLAN, MARK ASTON, BOARD OF TRUSTEES OF THE UNITED FOOD & COMMERCIAL WORKERS OF ARIZONA HEALTH AND WELFARE FUND, ADELE BRODY, MICHELLE CROSS, DONNA FRANCK, KRISTINE GADDIS, DAVID GREEN, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, JOHN H. IRONS, LOCAL 1199 NATIONAL BENEFIT FUND FOR HEALTH AND HUMAN SERVICES EMPLOYEES, MARIA LOCURTO, CAROLINE M. LOESCH, KIMBERLY MCCULLAR, LINDA K. MCINTYRE, MECHANICAL CONTRACTORS-UA LOCAL 119 WELFARE PLAN, THERESA MEYERS, PATRICIA NELSON, FRANCES NORRIS, PAPER, ALLIED-INDUSTRIAL, CHEMICAL AND ENERGY WORKERS INTERNATIONAL UNION, AFL-CIO, CLC, MARY ANN SCOTT, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, MAURICE STEWART, ANN STUART,

Appendix D

UNITED FOOD & COMMERCIAL WORKERS AND PARTICIPATING FOOD INDUSTRY EMPLOYERS TRI-STATE HEALTH & WELFARE FUND, and VISTAHEALTHPLAN, INC.,

Plaintiffs-Appellants,

v.

BAYER AG and BAYER CORP.,

Defendants-Appellees,

and

HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (doing business as Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,

Defendants-Appellees,

and

BARR LABORATORIES, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Eastern District of New York, in 1:00-MD-01383, Senior Judge David G. Trager.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, and a response thereto having been invited by the court and filed by the Appellees, and the petition for rehearing

and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 30, 2008.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 12/23/2008

APPENDIX E — PERTINENT TEXT OF RELEVANT STATUTES

SHERMAN ANTITRUST ACT

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

Section 2: Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2.

Appendix E

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("HATCH-WAXMAN ACT"), AS AMENDED

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * *

(B) Notice of opinion that patent is invalid or will not be infringed

(i) *Agreement to give notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) *Timing of notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) *Recipients of notice.* An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) *Contents of notice.* A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

* * *

(5) **(A)** Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III). (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information

was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II). In such an action, each of the parties shall reasonably cooperate in expediting the action.

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(iv) *180-day exclusivity period*

(I) *Effectiveness of application.* Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) *Definitions.* In this paragraph:

(aa) *180-day exclusivity period.* The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) *First applicant.* As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) *Substantially complete application.* As used in this subsection, the term "substantially complete application" means an application under this subsection

that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) *Tentative approval*

(AA) *In general*

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) *Limitation*

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) *Civil action to obtain patent certainty*

(i) *Declaratory judgment absent infringement action*

(I) *In general*

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No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) *Filing of civil action*

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the

patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) *Offer of confidential access to application*

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person

provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) *Counterclaim to infringement action*

(I) *In general*

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) *No independent cause of action*

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) *No damages.* An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) *Forfeiture of 180-day exclusivity period*

(i) *Definition of forfeiture event.* In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) *Failure to market.* The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which

the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) *Withdrawal of application.* The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

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(III) *Amendment of certification.* The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) *Failure to obtain tentative approval.* The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) *Agreement with another applicant, the listed drug application holder, or a patent owner.* The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) *Expiration of all patents.* All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) *Forfeiture.* The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) *Subsequent applicant.* If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall

be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The

approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than

bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

* * *

21 U.S.C. §355(j).

(June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan

No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub.L. 86-507, § 1(18), 74 Stat. 201; Oct. 10, 1962, Pub.L. 87- 781, Title I, §§ 102(b) to (d), 103(a), (b), 104(a) to (d)(2), 76 Stat. 781- 783, 784, 785; Aug. 16, 1972, Pub.L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub.L. 98-417, Title I, §§ 101, 102(a) to (b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub.L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub.L. 103-80, § 3(n), 107 Stat. 777; Nov. 21, 1997, Pub.L. 105-115, Title I, §§ 115(a), (b), 117, 119, 120, 124(a), 111 Stat. 2313, 2315, 2316, 2318, 2324; Nov. 29, 1999, Pub.L. 106-113, Div. B, § 1000(a)(9) [Title IV, § 4732(b)(11)], 113 Stat. 1536, 1501A-584; Jan. 4, 2002, Pub.L. 107-109, § 15(c)(1), 115 Stat. 1420; Dec. 3, 2003, Pub.L. 108-155, § 2(b)(1), 117 Stat. 1941; Dec. 8, 2003, Pub.L. 108-173, Title XI, §§ 1101(a), (b), 1102(a), 1103(a), 117 Stat. 2448, 2452, 2457, 2460.)

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in

paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior

to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text

of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003).